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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

Enforcement Committee Report

Randy Kajioka, PharmD, Chair
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ENFORCEMENT COMMITTEE REPORT AND ACTION

a. Report of the Meeting Held December 6, 2010

1. FOR DISCUSSION: Requests for Exemptions from 16 California Code of Regulations Section 1707.5, Label Requirements for Prescription Drug Containers, as Authorized by Section 4076.5 (SB 1489, Negrete-McLeod, Chapter 653, Statutes of 2010)

Attachment 1

Effective January 1, 2011, the board's requirements for patient-centered labels went into effect as 16 California Code of Regulations section 1707.5. A copy of the final text for the regulation is provided in **Attachment 1**.

Also effective January 1, 2011, provisions enacted by SB 1489 (Senate Business and Professions Committee, Chapter 653, Statutes of 2010) as amendments to Business and Professions Code section 4076.5, allow the board to exempt from the labeling requirements prescriptions dispensed to patients in certain environments. The exemptions are provided as subdivisions (d) and (e) below.

> SEC. 25.1. Section 4076.5 of the Business and Professions Code is amended to read:
>
> 4076.5. (a) The board shall promulgate regulations that require, on or before January 1, 2011, a standardized, patient-centered, prescription drug label on all prescription medicine dispensed to patients in California.
> (b) To ensure maximum public comment, the board shall hold public meetings statewide that are separate from its normally scheduled hearings in order to seek information from groups representing consumers, seniors, pharmacists or the practice of pharmacy, other health care professionals, and other interested parties.
> (c) When developing the requirements for prescription drug labels, the board shall consider all of the following factors:
> (1) Medical literacy research that points to increased understandability of labels.
> (2) Improved directions for use.
> (3) Improved font types and sizes.
> (4) Placement of information that is patient-centered.
> (5) The needs of patients with limited English proficiency.

(6) The needs of senior citizens.
(7) Technology requirements necessary to implement the standards.
(d) The board may exempt from the requirements of regulations promulgated pursuant to subdivision (a) prescriptions dispensed to a patient in a health facility, as defined in Section 1250 of the Health and Safety Code. if the prescriptions are administered by a licensed health care professional. Prescriptions dispensed to a patient in a health facility that will not be administered by a licensed health care professional or that are provided to the patient upon discharge from the facility shall be subject to the requirements of this section and the regulations promulgated pursuant to subdivision (a). Nothing in this subdivision shall alter or diminish existing statutory and regulatory informed consent, patients' rights, or pharmaceutical labeling and storage requirements, including, but not limited to, the requirements of Section 1418.9 of the Health and Safety Code or Section 72357, 72527, or 72528 of Title 22 of the California Code of Regulations.
(e) (1) The board may exempt from the requirements of regulations promulgated pursuant to subdivision (a) a prescription dispensed to a patient if all of the following apply:
(A) The drugs are dispensed by a JCAHO-accredited home infusion or specialty pharmacy.
(B) The patient receives health-professional-directed education prior to the beginning of therapy by a nurse or pharmacist.
(C) The patient receives weekly or more frequent followup contacts by a nurse or pharmacist.
(D) Care is provided under a formal plan of care based upon a physician and surgeon's orders.
(2) For purposes of paragraph (1), home infusion and specialty therapies include parenteral therapy or other forms of administration that require regular laboratory and patient monitoring.
(f) (1) On or before January 1, 2010, the board shall report to the Legislature on its progress under this section as of the time of the report. (2) On or before January 1, 2013, the board shall report to the Legislature the status of implementation of the prescription drug label requirements adopted pursuant to this section.

Note: for reference, the text of Health and Safety Code section 1250 is provided in Attachment 1

This law directs that the board "may exempt," so to allow such an exemption, the board will need to promulgate regulations.

At the December 2010 meeting, the Enforcement Committee heard presentations from two groups seeking an exemption from the labeling requirements for their specialized patient populations. One was from an infusion pharmacy and the other represented skilled nursing facilities. Neither presentation provided the committee with sufficient information to act to recommend a waiver to the board. However, the committee invited the two groups back to present additional information. The minutes of the meeting detail these presentations and the discussion. The committee asked that companies interested in seeking an exemption provide data or samples to support their request. And that request contains at least (1) an explanation as to why the company cannot

comply with the new requirements and (2) information regarding policies or procedures in place that address the policy concerns behind the adopted regulations.

Since the December Enforcement Committee Meeting, the board's executive officer has received two more exemption requests (to exempt radiologic pharmacies, and to exempt parenteral nutrition labeling). These requests also will be scheduled for the next Enforcement Committee Meeting.

2. FOR INFORMATION: Discussion Regarding Reporting Financial Settlements to the Board Under Sections 801-804 of the California Business and Professions Code

Relevant Statutes

Business and Professions Code sections 801-802 generally establish reporting requirements by professional liability insurers and by licensees without professional liability insurance, of any settlement or arbitration award over $3,000 of any claim or action for damages or death or personal injury caused by a licensee's negligence, error, or omission in practice, or by his or her rendering of unauthorized professional services.

Section 803 of the Business and Professions Code requires that the clerk of a court that renders a judgment that a licensee has committed a crime, or is liable for any death or personal injury resulting in a judgment for an amount over $30,000.00 caused by the licensee's negligence, error or omission in practice, or his or her rendering of unauthorized professional services, report that judgment to the Board within 10 days after the judgment is entered.

Background

The board recently undertook efforts to ensure that licensees and insurance companies are aware of their responsibilities to report to the board pursuant to sections 801 to 804 of the California Business and Professions Code.

In the September 2010 *The Script* the board provided a notice of these reporting requirements. A copy of this article follows this page.

Reporting to the board of these settlements is rare. In 2009/10, the board received 2,331 complaints. Only 11 complaints were reports under these sections.

In 2009, there were approximately 360 million prescriptions filled and dispensed in California by pharmacies. The board received notice from patients and from other sources of 307 medication errors during 2009/10. This further indicates the high degree of under-reporting under these statutory sections.

Committee Discussion/Action

The committee discussed the reporting requirements. The committee suggested that the board work with the Department of Insurance and the Department of Managed Health Care to achieve better compliance.

The committee did not take action on this item.

3. FOR INFORMATION: Updated on the Board's Efforts to Implement Components of the Department of Consumer Affairs Consumer Protection Enforcement Initiative

Background

Beginning in July 2009, the Department of Consumer Affairs has been working with health care boards to improve capabilities to investigate and discipline errant licensees to protect the public from harm. These results yielded the Consumer Protection Enforcement Initiative (CPEI). The CPEI was comprised of a three pronged solution designed to ensure that investigations were completed and final action taken against licensees within 12 – 18 months. The solution included legislative changes designed to remove barriers to investigations, a new computer system that would meet the board's needs to collect information and monitor performance, and additional staff resources.

Many of the legislative changes identified by the department were incorporated into SB 1111 (Negrete McLeod, 2010). This bill failed passage early in the year during its first policy committee. The department identified provisions in the bill that could be implemented through regulation and has encouraged boards to develop language and initiate the rulemaking process.

In addition to working with the department on a department wide solution, the board also identified statutory changes that would specifically address pharmacy related issues. Language for these provisions was discussed during the January 2010 Board Meeting, and the board voted to pursue the changes. Because of the timing with the legislative cycle, these provisions were not pursued this year.

Summary of Board Action

More recently, during the June 2010 Board Meeting, the board discussed proposed regulatory language developed by counsel, designed to implement the provisions requested by the department. The board expressed concern about many of the provisions and with one exception, did not take action on the items.

Recent Board Action

During the October 2010 Board Meeting, board members were advised that the department continues to encourage boards to pursue regulations changes that were previously incorporated into SB 1111. Consistent with the department's request, the board considered several proposed regulation changes:

1. Amendments to section 1760 regarding standardized disciplinary guidelines for violations dealing with sexual contact. As drafted, the change would provide that findings of sexual contact with a patient, client or customer or conviction of a sex offense would be grounds for revocation by the Administrative Law Judge (ALJ); however, the board would have discretion to impose a lesser penalty under this proposal. **Board Action**: The board rejected this proposal.

2. Amendments to section 1762 regarding the proposed amendments to this section that would specify that certain acts would constitute unprofessional conduct including: gag clauses in a civil suit settlement; failure to provide information as requested by the board; failure to comply with a court order or subpoena for records; and failure to notify the board about an arrest, indictment, conviction or discipline as specified. The section

also would specify that the board is authorized to revoke a license or deny an application for an act requiring an individual to register as a sex offender.
Board Action: The board voted to direct staff to modify amendments to section 1762 to specify records within the board's purview and to bring revisions back to the Enforcement Committee for possible recommendation to the board. (Additional information on this item will be provided under the next agenda item.)

3. Amendment to section 1769 – Application Review and Criteria for Rehabilitation. The proposed amendment would allow the board to request that an applicant for licensure undergo an examination as specified to determine if the applicant is safe to practice. The board voted to require that once it has been determined that an applicant is to be evaluated; the evaluation shall be completed within 60 days. Within 60 days of the evaluation, the report must be received from the evaluator.
Board Action: The board voted to amend the proposed language for section 1769 to require that once it has been determined that an applicant is to be evaluated, the evaluation and report shall be completed within 60 days and directed staff to take all necessary steps to initiate the formal rulemaking process.

4. FOR INFORMATION: Proposed Amendment to California Code of Regulations Section 1762, Regarding submission of Records to the Board

Attachment 2

Background
Provided under the previous item is general background on this proposal. Under consideration for the board is the addition to Title 16 CCR Section 1762 which would define activities that constitute unprofessional conduct.

Committee Discussion/Action:
The committee discussed the proposed language to amend section 1762. To facilitate discussion on each item, the committee discussed each subdivision separately.

Specifically, the proposed language would establish the following:

- Section 1762(a) would specify that that gag clauses in a civil suit settlement would constitute unprofessional conduct.
- Section 1762(b) would specify that failure without lawful excuse to provide information as requested by the board within 15 days of the receipt of the request or as specified would constitute unprofessional conduct.
- Section 1762(c) would specify that failure to comply with a court order or subpoena for records would constitute unprofessional conduct.
- Section 1762(d) would specify that failure to notify the board about an arrest, indictment, conviction or discipline as specified would constitute unprofessional conduct.
- Section 1762(e) would specify that the board is authorized to revoke a license or deny an application for an act requiring an individual to register as a sex offender.

A copy of the full proposed language is provided in **Attachment 2.**

MOTION: ENFORCEMENT COMMITTEE: Recommend to the board to initiate a rulemaking to adopt the proposed text for §1762(a).

MOTION: ENFORCEMENT COMMITTEE: Recommend to the board to initiate a rulemaking to adopt the proposed text for §1762(b).

MOTION: ENFORCEMENT COMMITTEE: Recommend to the board to initiate a rulemaking to adopt the proposed text for §1762(c).

MOTION: ENFORCEMENT COMMITTEE: Direct staff to rework the proposed text for §1762(d)(4) for consideration by the committee.

MOTION: ENFORCEMENT COMMITTEE Recommend to the board to initiate a rulemaking to adopt the proposed text for §1762(e).

5. FOR DISCUSSION AND POSSIBLE ACTION: DCA's Recommendations of the Substance Abuse Coordination Committee, Pursuant to SB 1441, for the Pharmacists Recovery Program

Attachment 3

Background

Senate Bill 1441 created the Substance Abuse Coordination Committee (SACC) and required that this committee, by January 1, 2010, formulate uniform and specific standards in specified areas that each healing arts board must use in dealing with substance-abusing licensees, whether or not a board chooses to have a formal diversion program.

To facilitate implementation of these standards, the DCA created a workgroup in 2009 consisting of staff from each of the healing arts boards to draft recommended standards for SACC consideration during public meetings.

Below is a brief description of each of the 16 standards in their current form.

1. Clinical diagnostic evaluation
   - Specifies that if a licensee in a diversion program or on probation is required to undergo a clinical evaluation it shall comply with :
     i. Qualifications for the licensed practitioner performing the evaluation
     ii. Acceptable standards for such evaluations
     iii. Identified elements of the report
     iv. Timeframes to complete the process and prohibition of the evaluator having a financial relationship, etc. with the licensee.
2. Temporary removal of practice for clinical evaluation
   - Specifies that board will issue a cease practice order during the evaluation and review of the results by board staff.
   - Specifies that the licensee will be subject to random drug testing at least two times per week.
   - Sets forth the evaluation criteria that must be considered by the diversion or probation manager when determining if a licensee is safe to return to work and under what conditions.
3. Communication with a licensee's employer, if applicable

- Requires a licensee to notify the board of the names, physical addresses, mailing addresses and telephone numbers of all employers.
- Requires a licensee to give written consent authorizing the board and employers and supervisors to communicate regarding the licensee's work status, performance and monitoring.

4. Drug testing
    - Sets forth a minimum testing frequency of 104 random drug tests per year for the first year and a minimum of 50 random drug tests per year (from then on).
    - Specifies that testing shall be observed; conducted on a random basis, as specified; and may be required on any day, including weekends or holidays.
    - Requires licensees to check daily to determine if testing is required and specifies that the drug test shall be completed on the same day as notification.
    - Establishes criteria for the collection sites and laboratories processing the results.
5. Group meeting attendance
    - Sets forth the evaluation criteria that must be considered when determining the frequency of group support meetings.
    - Specifies the qualifications and reporting requirements for the meeting facilitator.
6. Type of treatment
    - Sets for the evaluation criteria that must be considered when determining whether inpatient, outpatient, or other type of treatment is necessary.
7. Worksite monitoring
    - Allows for the use of worksite monitors.
    - Specifies the criteria for a worksite monitor.
    - Establishes the methods of monitoring that must be performed by the worksite monitor.
    - Sets forth the reporting requirements by the worksite monitor; specifies that any suspected substance abuse must be verbally reported to the board and the licensee's employer within one business day; and specifies that a written report must be provided to the board within 48 hours of the occurrence.
    - Requires the licensee to complete consent forms and sign an agreement with the worksite monitor and board to allow for communication.
8. Positive drug test
    - Requires the board to issue a cease practice order to a licensee's license and notify the licensee, employee and worksite monitor that the licensee may not work.
    - Specifies that after notification, the board should determine if the positive drug test is evidence of prohibited use and sets forth the criteria the board must follow when making such a determination.
    - Specifies that if the board determines that it was not a positive drug test, it shall immediately lift the cease practice order.
9. Ingestion of a banned substance
    - Specifies that when a board confirms a positive drug test as evidence of use of a prohibited substance, the licensee has committed a major violation.
10. Consequences for major and minor violations
    - Specifies what constitutes a major violation including: failure to complete a board ordered program or undergo a clinical diagnostic evaluation; treating patients while under the influence of drugs/alcohol, and drug/alcohol related acts which would constitute a violation of the state/federal laws, failure to undergo drug testing,

confirmed positive drug test, knowingly defrauding or attempting to defraud a drug test.
- Specifies the consequences for a major violation including: issuing a cease practice order to the licensee; requiring a new clinical evaluation; termination of a contract/agreement; referral for disciplinary action.
- Specifies what constitutes a minor violation including: untimely receipt of required documentation; unexcused group meeting absence; failure to contact a monitor when required; any other violations that does not present an immediate threat to the violator or the public.
- Specifies the consequences for a minor violation including: removal from practice; practice restrictions; required supervision; increased documentation; issuance of a citation and fine or working notice; re-evaluation/testing; other actions as determined by the board.

11. Return to full time practice
    - Establishes the criteria to return to full time practice, including demonstrated sustained compliance, demonstrated ability to practice safely, negative drug screens for at least six months, two positive worksite monitor reports and compliance with other terms and conditions of the program.
12. Unrestricted practice
    - Establishes the criteria for a licensee to request unrestricted practice including sustained compliance with a disciplinary order, successful completion of the recovery program, consistent and sustained participation in recovery activities, demonstrated ability to practice safely and continued sobriety of three to five years, as specified.
13. Private-sector vendor
    - Specifies that the vendor must report any major violation to the board within one business dayand any minor violation within five business days.
    - Establishes the approval process for providers or contractors that work with the vendor consistent with the uniform standards.
    - Requires the vendor to discontinue the use of providers or contractors that fail to provide effective or timely services as specified.
14. Confidentiality
    - For any participant in a diversion program whose license is on an inactive status or has practice restrictions, requires the board to disclose the licensee's name and a detailed description of any practice restrictions imposed.
    - Specifies that the disclosure will not include that the restrictions are as a result of the licensee's participation in a diversion program.
15. Audits of private-sector vendor
    - Requires an external independent audit every three years of a private-sector vendor providing monitoring services.
    - Specifies that the audit must assess the vendor's performance in adhering to the uniform standards and requires the reviewer to provide a report to the board by June 30 of each three year cycle.
    - Requires the board and department to respond to the findings of the audit report.
16. Measurable criteria for standards
    - Establishing annual reporting to the department and Legislature and details the information that must be provided in the report.
    - Sets forth the criteria to determine if the program protects patients from harm and is effective in assisting licensees in recovering from substance abuse in the long term.

The most recent version of the standards was approved in April 2010. During the April 2010 committee, the director established a subcommittee to re-evaluate the provisions contained within Uniform Standard 4.

The subcommittee met on August 4, 2010 but did not complete its work. A subsequent meeting was scheduled for September 24, 2010, however that meeting was cancelled. **Attachment 3** contains a copy of the standards in their current form.

Committee Discussion/Action
The committee discussed in general the uniform standards as well as the process used to develop them. The committee was advised that some of the proposed changes to the Disciplinary Guidelines would facilitate implementation of portions of these standards.

The committee did not take action on this item.

During this meeting the board may wish to provide staff with direction on implementation. Board staff will be available to discuss each standard and the board's current process.

6. FOR DISCUSSION and POSSIBLE ACTION: Proposed Modifications to the Board's *Disciplinary Guidelines*

Attachment 4

Relevant Regulation
California Code of Regulations Section 1760 requires the board to consider disciplinary guidelines when reaching a decision on a disciplinary action. This regulation section was last amended in May 2009.

Background
During the October Board Meeting, the board voted to direct staff to work on updating the Disciplinary Guidelines for the board. Staff has initiated work on identification of proposed changes, many of which have been developed by counsel, but there is still additional work that needs to be done. In addition to identifying changes to the language, the board will be asked to consider a reorganization of the guidelines to facilitate better understanding and remove duplication.

Committee Discussion/Action
The committee was provided with draft proposals and was advised that work on the guidelines will continue over the next several months and will be discussed during the next committee meeting for possible action. The committee considered if a subcommittee should be established to assist in this process and discussed the Pharmacists Recovery Program.

Attachment 4 contains a copy of the draft language developed thus far. Proposed changes resulting from the uniform standards at noted.

The committee did not take action on this item.

7. Question and Answer Document Explaining the Board's Implementation of 16 California Code of Regulations Sections 1735-1735.8, Pharmacies That Compound and Sections 1751-1751.8 Pharmacies that Compound Sterile Injectable Medications

Attachment 5

Relevant Regulations
Sections 1735 – 1735.8 establish requirements for pharmacies that compound medicine.

Sections 1751 - 1751.8 establish requirements for pharmacies that compound sterile injectable medications.

Background
Effective July 7, 2010, new and amended regulations took effect regarding pharmacies that compound medications as well as pharmacies that compound sterile injectable medications.

Since the approval of these regulations, board staff has been educating licensees on the requirements. Additionally, during enforcement committee meetings, Supervising Inspector Robert Ratcliff has been providing a question and answer session on the new compounding regulations. During the October 2010 Board Meeting, the board voted to create a subcommittee to further vet the questions and answers received thus far, as well as to respond to any new questions.

The subcommittee, comprised of Dr. Kajioka, Dr. Schell, Dr. Dang, Dr. Ratcliff and Ms. Herold. The subcommittee met January 5, 2011.

Attachment 5 contains the questions and answers that are posted on the board's web site.

Committee Discussion/Action:
The committee discussed the Q&A's and requested that future questions be submitted in writing and forwarded to the subcommittee to evaluate.

The committee did not take action on this item.

8. FOR INFORMATION: Discussion on Whether Patients Should be Allowed to Take Their Multi-Dose Medications Home Upon Discharge from a Hospital

Attachment 6

Several weeks ago, the executive officer met with representatives of drug manufacturer Sanofi-Aventis regarding the disposal of multi-dose containers of medication ordered for patients in hospitals that are not allowed to go home with patients at discharge because they are not labeled for patient self use. These multi-dose products include inhalers, eye drops, insulin, topical creams that are ordered for the patient during a hospital stay but are not in the patient's control while the patient is in the hospital. Because they are not labeled for patient self-use, they are destroyed when the patient is discharged, even though the patient has been charged for the whole product. **Attachment 6** is an article providing an example of this problem.

Committee Action/Discussion
During the meeting, the committee heard a presentation by Deanne Calvert, JD, representing Sanofi Aventis. Ms. Calvert discussed the disposal of multi-dose containers of medication ordered for patients in hospitals that are not allowed to go home with patients at discharge because they are not labeled for patient self use. She stated that these multi-dose products include inhalers, eye drops, insulin, and topical creams that are ordered for the patient during a hospital stay but are not in the patient's control while the patient is in the hospital. Ms. Calvert advised that because they are not labeled for patient self-use, they are destroyed when the patient is discharged, even though the patient has been charged for the whole product.

Ms. Calvert discussed a project by Spectrum Health, a hospital system in Michigan, which evaluated whether it was feasible to implement a system that would allow patients to take home these medications. She indicated that this project was successful in identifying a generic preprinted label to be added to the patient barcode label that would meet all federal and Michigan state regulations regarding properly labeling medication for dispensing at discharge.

Ms. Calvert discussed outreach efforts for this process in other states and sought input regarding any California laws that would prohibit this process.

The committee did not take action on this item.

9. FOR INFORMATION: Provision of the First Ethics Course Pursuant to 16 California Code of Regulations Section 1773.5

Relevant Regulations
California Code of Regulations Section 1773.5 establishes the criteria for an ethic course that may be required as a term and condition of probation, license reinstatement or as abatement for a citation and fine. This regulation section took effect September 3, 2009

Update
In mid-November, the Institute for Medical Quality provided the first ethics course for pharmacists under the requirements specified in 16 California Code of Regulations sections 1773 and 1773.5. We believe that 12 pharmacists (ordered to complete this course as a condition of their probation) were enrolled. The course will follow these individuals over the next 12 months. Periodic reports of the progress of this course will be provided to the committee and board in the future.

There is a second course provider interested in providing a course that meets the parameters of section 1773.5; however, we are not aware that this course has actually been provided or scheduled at this time.

Whereas the board is not specifically involved in the course provided, and because it is a new program, the board will be kept updated as probationers take and complete these courses.

Committee Action/Discussion
The committee did not take action on this item.

10. FOR INFORMATION and DISCUSSION: Review and Discussion of Enforcement Statistics and Performance Standards of the Board of Pharmacy

Attachment 7

Attachment 7 contain the second quarter's reporting on the DCA's enforcement performance measures. The department has developed the reporting parameters for this report. Also provided in this attachment are the board's strategic plan update and quarterly enforcement statistics.

11. FOR DISCUSSION AND POSSIBLE ACTION: Summary of Meeting of December 6, 2010

Attachment 8

A copy of the meeting summary is provided in **Attachment 8.**

b. FOR ACTION: Request from University Specialty Pharmacy to Renew its Board Waiver from 16 California Code of Regulations Section 1713(b) to Provide Synagis Prescription Medicine to Home Health Patients

Attachment 9

University Specialty Pharmacy has requested that the board renew its waiver of 16 California Code of Regulations Section 1713(a) under the waiver authority specified in section 1713(b).

The specific request is to allow University Specialty Pharmacy to deliver "dispensed" Synagis medication to a licensed home health agency for administration to the patient by the home health agency at the patient's home. This request is for re-approval of a three-year waiver approved by the board in late 2007.

A representative of University Specialty Pharmacy will attend this board meeting to make the request and answer questions.

The specific parameters of the request are provided in the documents provided as **Attachment 9**. An excerpt of the request is provided below:

1. The medication involved (*Synagis*®) requires refrigeration, and as a result, must at all times be stored either in a refrigerator or in a cooler to maintain its integrity. By allowing these medications to be delivered to the administering professional nurses rather than direct delivery to patients, better control can be maintained, avoiding the accidental and unattended delivery of the drugs (e.g. being left on a doorstep) and the mishandling of the subject drugs once in the residence.

2. Transportation of the prescriptions to the designated nurses will be either delivery driver or via overnight courier. The nurses will, in turn, directly deliver the prescriptions to the patients' homes upon receipt. At all times following its delivery, the prescribed medication will be under the direct supervision of the nurse(s) who receive it.

3. If consultation is needed regarding the delivered prescriptions, it will be available primarily through written drug information (provided in English and Spanish) and a pharmacist will be available at all times for further consultation via phone.

This item was not heard by the Enforcement Committee. Should the board wish to act on this request, a motion and second will be required during the meeting.

The relevant excerpt of the authorizing regulation is provided below for reference.

1713. Receipt and Delivery of Prescriptions and Prescription Medications Must be to or from Licensed Pharmacy

(a) Except as otherwise provided in this Division, no licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy.

(b) A licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or at the hospital, institution, medical office or clinic at which the patient receives health care services. In addition, the Board may, in its sole discretion, waive application of subdivision (a) for good cause shown.

(c) A patient or the patient's agent may deposit a prescription in a secure container that is at the same address as the licensed pharmacy premises. The pharmacy shall be responsible for the security and confidentiality of the prescriptions deposited in the container.

(d) A pharmacy may use an automated delivery device to deliver previously dispensed prescription medications provided: . . .

c. FOR DISCUSSION AND POSSIBLE ACTION: Discussion and Review of Proposed Written Guidance to Pharmacies and Prescribers on the Transmission and Receipt of Electronic Controlled Substances Prescriptions Pursuant to the Drug Enforcement Administration's Interim Final Rule

Attachment 10

Early in 2010, the Drug Enforcement Administration released its Interim Final Rule on that agency's requirements for the electronic transmission of prescriptions for controlled drugs. This interim rule took effect in June 2010.

The DEA's requirements for e-prescribing of controlled drugs is laid out in a 330 page document that is both detailed and highly technical. In order to provide information to board licensees about the requirements contained in this document, Board Liaison and Deputy Attorney General Joshua Room developed a guidance document. This document is provided in **Attachment 10**.

Before starting this process, the executive officer also approached the executive officer of the Medical Board to see if they would be interested in a similar guidance document for their licensees. They were interested, and Mr. Room worked in conjunction with an attorney from the Medical Board's DAGs to produce the draft document in the meeting materials.

At this meeting, the board will have an opportunity to discuss the document as part of the review process.

d. FOR DISCUSSION AND POSSIBLE ACTION: Review and Comments on CalRecycle's Report to the Legislature on the Evaluation of Home-Generated Pharmaceutical Programs, as Revised January 19, 2011

Attachment 11

In 2007, the Legislature enacted SB 966 (Simitian, Chapter 542). Among other things, this law directed that until January 1, 2013, the California Integrated Waste Management Board (now CalReycle) shall develop, in consultation with appropriate state, local, and federal agencies, model programs for the collection and proper disposal of pharmaceutical drug waste.

This law required a report to the Legislature in December 2010. The legislative report must:

> . . . include an evaluation of the model programs for efficacy, safety, statewide accessibility, and cost effectiveness. The report shall include the consideration of the incidence of diversion of drugs for unlawful sale and use, if any. The report also shall provide recommendations for the potential implementation of a statewide program and statutory changes.

CalRecycle's report is now complete and a copy of this report is provided as **Attachment 11**.

The board provided draft comments to an initial version of this report in August 2010. These comments are also provided as **Attachment 11.**

The board may want to discuss and submit additional comments in response to this CalRecycle report.

e. FOR INFORMATION: DEA's Requests for Comments on Parameters for the Take Back of Unwanted Prescription Medication from Patients for Destruction

Late in December 2010, board staff learned that the Drug Enforcement Administration (DEA) would be conducting a public meeting on January 19 and 20, 2011 to discuss procedures for the surrender of unwanted controlled substances by ultimate users and long-term care facilities. This hearing would be a step toward the development of regulations to implement the Secure and Responsible Drug Disposal Act of 2010. At that time, the DEA announced that they were seeking oral and written comment at the meeting; written comments were due January 12. The DEA stated that a transcript from this public meeting would be made available at the DEA Diversion Control Program Web site, http://www.deadiversion.usdoj.gov.

Due to the short notice period, which coincided with the holidays, no written comments were submitted from the Board of Pharmacy.

The DEA requested the following comments:

- The process of the disposal of unwanted controlled substances could create new and unwanted avenues for diversion. What is the safest manner, in your opinion, to dispose of unwanted controlled substances while preventing diversion?
- Please explain why you believe the solution you propose would protect the public health and safety and would curtail diversion.
- Do you foresee any specific obstacles to the disposal of controlled substances in your community or geographical area? If so, what are they?
- How is the disposal of controlled substances affected by State and local laws and regulations?

The board may wish to discuss these components at this meeting.

f. FOR INFORMATION: <u>Transition Issues Surrounding the New Vendor for California's CURES Program</u>

Attachment 12

In mid-December, the California Department of Justice advised California pharmacies that effective January 1, 2011, all pharmacies were to electronically submit their data regarding controlled substances dispensed to a new vendor. This was very short notice. A copy of the notice documents sent to pharmacies is provided in **Attachment 12**.

The board has received a few complaints regarding transmission of data to the new vendor. These complaints typically are referred to the California Department of Justice.

At this meeting, the board will hear any comments from the public regarding the transition and new vendor.

The board does enforce the requirement that pharmacies transmit data to CURES each week.

g. FOR INFORMATION: <u>Second Quarterly Report of the Committee's Goals for 2010/11</u>

ATTACHMENT 13

Attachment 13 contains the second quarter's report on the committee's strategic plan.

Attachment 1 –

Section 1707.5

§ 1707.5. Patient-Centered Labels for Prescription Drug Containers; Requirements

(a) Labels on drug containers dispensed to patients in California shall conform to the following format:

(1) Each of the following items shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a 10-point sans serif typeface or, if requested by the consumer, at least a 12-point typeface, and listed in the following order:

(A) Name of the patient

(B) Name of the drug and strength of the drug. For the purposes of this section, “name of the drug” means either the manufacturer’s trade name of the drug, or the generic name and the name of the manufacturer.

(C) The directions for the use of the drug.

(D) The condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription.

(2) For added emphasis, the label shall also highlight in bold typeface or color, or use blank space to set off the items listed in subdivision (a)(1).

(3) The remaining required elements for the label specified in section 4076 of the Business and Professions Code, as well as any other items of information appearing on the label or the container, shall be printed so as not to interfere with the legibility or emphasis of the primary elements specified in paragraph (1) of subdivision (a). These additional elements may appear in any style, font, and size typeface.

(4) When applicable, directions for use shall use one of the following phrases:

(A) Take 1 [insert appropriate dosage form] at bedtime

(B) Take 2 [insert appropriate dosage form] at bedtime

(C) Take 3 [insert appropriate dosage form] at bedtime

(D) Take 1 [insert appropriate dosage form] in the morning

(E) Take 2 [insert appropriate dosage form] in the morning

(F) Take 3 [insert appropriate dosage form] in the morning

(G) Take 1 [insert appropriate dosage form] in the morning, and Take 1 [insert appropriate dosage form] at bedtime

(H) Take 2 [insert appropriate dosage form] in the morning, and Take 2 [insert appropriate dosage form] at bedtime

(I) Take 3 [insert appropriate dosage form] in the morning, and Take 3 [insert appropriate dosage form] at bedtime

(J) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, and 1 [insert appropriate dosage form] in the evening

(K) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, and 2 [insert appropriate dosage form] in the evening

(L) Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at noon, and 3 [insert appropriate dosage form] in the evening

(M) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, 1 [insert appropriate dosage form] in the evening, and 1 [insert appropriate dosage form] at bedtime

(N) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, 2 [insert appropriate dosage form] in the evening, and 2 [insert appropriate dosage form] at bedtime

(O) Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at noon, 3 [insert appropriate dosage form] in the evening, and 3 [insert appropriate dosage form] at bedtime

(P) If you have pain, take __ [insert appropriate dosage form] at a time. Wait at least __ hours before taking again. Do not take more than __ [appropriate dosage form] in one day

(b) By October 2011, and updated as necessary, the board shall publish on its Web site translation of the directions for use listed in subdivision (a)(4) into at least five languages other than English, to facilitate the use thereof by California pharmacies.

(c) The board shall collect and publish on its Web site examples of labels conforming to these requirements, to aid pharmacies in label design and compliance.

(d) The pharmacy shall have policies and procedures in place to help patients with limited or no English proficiency understand the information on the label as specified in subdivision (a) in the patient's language. The pharmacy's policies and procedures shall be specified in writing and shall include, at minimum, the selected means to identify the patient's language and to provide interpretive services in the patient's language. The pharmacy shall, at minimum, provide interpretive services in the patient's language, if interpretive services in such language are available, during all hours that the pharmacy is open, either in person by pharmacy staff or by use of a third-party interpretive service available by telephone at or adjacent to the pharmacy counter.

(e) The board shall re-evaluate the requirements of this section by December 2013 to ensure optimal conformance with Business and Professions Code section 4076.5.

(f) As used in this section, "appropriate dosage form" includes pill, caplet, capsule or tablet.

Authority cited: Sections 4005 and 4076.5, Business and Professions Code.
Reference: Sections 4005, 4076, and 4076.5, Business and Professions Code.

Health and Safety Code section 1250:

1250. As used in this chapter, "health facility" means any facility, place, or building that is organized, maintained, and operated for the diagnosis, care, prevention, and treatment of human illness, physical or mental, including convalescence and rehabilitation and including care during and after pregnancy, or for any one or more of these purposes, for one or more persons, to which the persons are admitted for a 24-hour stay or longer, and includes the following types:

(a) "General acute care hospital" means a health facility having a duly constituted governing body with overall administrative and professional responsibility and an organized medical staff that provides 24-hour inpatient care, including the following basic services: medical, nursing, surgical, anesthesia, laboratory, radiology, pharmacy, and dietary services. A general acute care hospital may include more than one physical plant maintained and operated on separate premises as provided in Section **1250**.8. A general acute care hospital that exclusively provides acute medical rehabilitation center services, including at least physical therapy, occupational therapy, and speech therapy, may provide for the required surgical and anesthesia services through a contract with another acute care hospital. In addition, a general acute care hospital that, on July 1, 1983, provided required surgical and anesthesia services through a contract or agreement with another acute care hospital may continue to provide these surgical and anesthesia services through a contract or agreement with an acute care hospital. The general acute care hospital operated by the State Department of Developmental Services at Agnews Developmental Center may, until June 30, 2007, provide surgery and anesthesia services through a contract or agreement with another acute care hospital. Notwithstanding the requirements of this subdivision, a general acute care hospital operated by the Department of Corrections and Rehabilitation or the Department of Veterans Affairs may provide surgery and anesthesia services during normal weekday working hours, and not provide these services during other hours of the weekday or on weekends or holidays, if the general acute care hospital otherwise meets the requirements of this section.

A "general acute care hospital" includes a "rural general acute care hospital." However, a "rural general acute care hospital" shall not be required by the department to provide surgery and anesthesia services. A "rural general acute care hospital" shall meet either of the following conditions:

(1) The hospital meets criteria for designation within peer group six or eight, as defined in the report entitled Hospital Peer Grouping for Efficiency Comparison, dated December 20, 1982.

(2) The hospital meets the criteria for designation within peer group five or seven, as defined in the report entitled Hospital Peer Grouping for Efficiency Comparison, dated December 20, 1982, and has no more than 76 acute care beds and is located in a census dwelling place of 15,000 or less population according to the 1980 federal census.

(b) "Acute psychiatric hospital" means a health facility having a duly constituted governing body with overall administrative and

professional responsibility and an organized medical staff that provides 24-hour inpatient care for mentally disordered, incompetent, or other patients referred to in Division 5 (commencing with Section 5000) or Division 6 (commencing with Section 6000) of the Welfare and Institutions **Code**, including the following basic services: medical, nursing, rehabilitative, pharmacy, and dietary services.

(c) "Skilled nursing facility" means a health facility that provides skilled nursing care and supportive care to patients whose primary need is for availability of skilled nursing care on an extended basis.

(d) "Intermediate care facility" means a health facility that provides inpatient care to ambulatory or nonambulatory patients who have recurring need for skilled nursing supervision and need supportive care, but who do not require availability of continuous skilled nursing care.

(e) "Intermediate care facility/developmentally disabled habilitative" means a facility with a capacity of 4 to 15 beds that provides 24-hour personal care, habilitation, developmental, and supportive health services to 15 or fewer persons with developmental disabilities who have intermittent recurring needs for nursing services, but have been certified by a physician and surgeon as not requiring availability of continuous skilled nursing care.

(f) "Special hospital" means a health facility having a duly constituted governing body with overall administrative and professional responsibility and an organized medical or dental staff that provides inpatient or outpatient care in dentistry or maternity.

(g) "Intermediate care facility/developmentally disabled" means a facility that provides 24-hour personal care, habilitation, developmental, and supportive health services to persons with developmental disabilities whose primary need is for developmental services and who have a recurring but intermittent need for skilled nursing services.

(h) "Intermediate care facility/developmentally disabled-nursing" means a facility with a capacity of 4 to 15 beds that provides 24-hour personal care, developmental services, and nursing supervision for persons with developmental disabilities who have intermittent recurring needs for skilled nursing care but have been certified by a physician and surgeon as not requiring continuous skilled nursing care. The facility shall serve medically fragile persons with developmental disabilities or who demonstrate significant developmental delay that may lead to a developmental disability if not treated.

(i) (1) "Congregate living health facility" means a residential home with a capacity, except as provided in paragraph (4), of no more than 12 beds, that provides inpatient care, including the following basic services: medical supervision, 24-hour skilled nursing and supportive care, pharmacy, dietary, social, recreational, and at least one type of service specified in paragraph (2). The primary need of congregate living health facility residents shall be for availability of skilled nursing care on a recurring, intermittent, extended, or continuous basis. This care is generally less intense than that provided in general acute care hospitals but more intense than that provided in skilled nursing facilities.

(2) Congregate living health facilities shall provide one of the following services:

(A) Services for persons who are mentally alert, persons with physical disabilities, who may be ventilator dependent.

(B) Services for persons who have a diagnosis of terminal illness, a diagnosis of a life-threatening illness, or both. Terminal illness means the individual has a life expectancy of six months or less as stated in writing by his or her attending physician and surgeon. A "life-threatening illness" means the individual has an illness that can lead to a possibility of a termination of life within five years or less as stated in writing by his or her attending physician and surgeon.

(C) Services for persons who are catastrophically and severely disabled. A person who is catastrophically and severely disabled means a person whose origin of disability was acquired through trauma or nondegenerative neurologic illness, for whom it has been determined that active rehabilitation would be beneficial and to whom these services are being provided. Services offered by a congregate living health facility to a person who is catastrophically disabled shall include, but not be limited to, speech, physical, and occupational therapy.

(3) A congregate living health facility license shall specify which of the types of persons described in paragraph (2) to whom a facility is licensed to provide services.

(4) (A) A facility operated by a city and county for the purposes of delivering services under this section may have a capacity of 59 beds.

(B) A congregate living health facility not operated by a city and county servicing persons who are terminally ill, persons who have been diagnosed with a life-threatening illness, or both, that is located in a county with a population of 500,000 or more persons may have not more than 25 beds for the purpose of serving persons who are terminally ill.

(C) A congregate living health facility not operated by a city and county serving persons who are catastrophically and severely disabled, as defined in subparagraph (C) of paragraph (2) that is located in a county of 500,000 or more persons may have not more than 12 beds for the purpose of serving persons who are catastrophically and severely disabled.

(5) A congregate living health facility shall have a noninstitutional, homelike environment.

(j) (1) "Correctional treatment center" means a health facility operated by the Department of Corrections and Rehabilitation, the Department of Corrections and Rehabilitation, Division of Juvenile Facilities, or a county, city, or city and county law enforcement agency that, as determined by the state department, provides inpatient health services to that portion of the inmate population who do not require a general acute care level of basic services. This definition shall not apply to those areas of a law enforcement facility that houses inmates or wards that may be receiving outpatient services and are housed separately for reasons of improved access to health care, security, and protection. The health services provided by a correctional treatment center shall include, but are not limited to, all of the following basic services: physician and surgeon, psychiatrist, psychologist, nursing, pharmacy, and dietary. A correctional treatment center may provide the following services: laboratory, radiology, perinatal, and any other services approved by the state department.

(2) Outpatient surgical care with anesthesia may be provided, if the correctional treatment center meets the same requirements as a surgical clinic licensed pursuant to Section 1204, with the exception

of the requirement that patients remain less than 24 hours.

(3) Correctional treatment centers shall maintain written service agreements with general acute care hospitals to provide for those inmate physical health needs that cannot be met by the correctional treatment center.

(4) Physician and surgeon services shall be readily available in a correctional treatment center on a 24-hour basis.

(5) It is not the intent of the Legislature to have a correctional treatment center supplant the general acute care hospitals at the California Medical Facility, the California Men's Colony, and the California Institution for Men. This subdivision shall not be construed to prohibit the Department of Corrections and Rehabilitation from obtaining a correctional treatment center license at these sites.

(k) "Nursing facility" means a health facility licensed pursuant to this chapter that is certified to participate as a provider of care either as a skilled nursing facility in the federal Medicare Program under Title XVIII of the federal Social Security Act or as a nursing facility in the federal Medicaid Program under Title XIX of the federal Social Security Act, or as both.

(l) Regulations defining a correctional treatment center described in subdivision (j) that is operated by a county, city, or city and county, the Department of Corrections and Rehabilitation, or the Department of Corrections and Rehabilitation, Division of Juvenile Facilities, shall not become effective prior to, or if effective, shall be inoperative until January 1, 1996, and until that time these correctional facilities are exempt from any licensing requirements.

(m) "Intermediate care facility/developmentally disabled-continuous nursing (ICF/DD-CN)" means a homelike facility with a capacity of four to eight, inclusive, beds that provides 24-hour personal care, developmental services, and nursing supervision for persons with developmental disabilities who have continuous needs for skilled nursing care and have been certified by a physician and surgeon as warranting continuous skilled nursing care. The facility shall serve medically fragile persons who have developmental disabilities or demonstrate significant developmental delay that may lead to a developmental disability if not treated. ICF/DD-CN facilities shall be subject to licensure under this chapter upon adoption of licensing regulations in accordance with Section 1275.3. A facility providing continuous skilled nursing services to persons with developmental disabilities pursuant to Section 14132.20 or 14495.10 of the Welfare and Institutions **Code** shall apply for licensure under this subdivision within 90 days after the regulations become effective, and may continue to operate pursuant to those sections until its licensure application is either approved or denied.

Attachment 2

Proposed addition of Section 1762. to Article 8 in Division 17 of Title 16 of the California Code of Regulations to read as follows:
(this whole section is new)

§1762. Unprofessional Conduct Defined

In addition to those acts detailed in Business and Professions Code Section 4301, the following shall also constitute unprofessional conduct:

(a) Including or permitting to be included any of the following provisions in an agreement to settle a civil dispute arising from the licensee's practice, whether the agreement is made before or after the filing of an action:

(1) A provision that prohibits another party to the dispute from contacting, cooperating, or filing a complaint with the board; or,

(2) A provision that requires another party to the dispute to attempt to withdraw a complaint the party has filed with the board.

(b) Failure <u>without lawful excuse</u> to provide records requested by the board within 15 days of the date of receipt of the request or within the time specified in the request, whichever is later, ~~unless the licensee is unable to provide the documents within this time period for good cause. For the purposes of this section, "good cause" includes physical inability to access the records in the time allowed due to illness or travel.~~

(c) Failure or refusal to comply with any court order issued in the enforcement of a subpoena, mandating the release of records to the board.

(d) Failure to report to the board, within 30 days, any of the following:

(1) The bringing of an indictment or information charging a felony against the licensee.

(2) The arrest of the licensee.

(3) The conviction of the licensee, including any verdict of guilty, or pleas of guilty or no contest, of any felony or misdemeanor.

(4) Any disciplinary action taken by another licensing entity or authority of this state or of another state or an agency of the federal government or the United States military.

(e) Commission of any act resulting in the requirement that a licensee or applicant registers as a sex offender. The board may revoke the license of any licensee and deny the application of any applicant who is required to register as a sex offender pursuant to Section 290 of the Penal Code or any other equivalent federal, state or territory's law that requires registration as a sex offender.

Authority cited: 4005, Business and Professions Code. Reference: Sections 726, 4300 and 4301 Business and Professions Code.

Attachment 3

Uniform Standards Regarding Substance-Abusing Healing Arts Licensees

Senate Bill 1441 (Ridley-Thomas)

Implementation by
Department of Consumer Affairs,
Substance Abuse Coordination Committee

Brian J. Stiger, Director
April 2010

STATE OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS

Substance Abuse Coordination Committee

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Amy Edelen, Veterinary Medical Board
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#1 SENATE BILL 1441 REQUIREMENT

Specific requirements for a clinical diagnostic evaluation of the licensee, including, but not limited to, required qualifications for the providers evaluating the licensee.

#1 Uniform Standard

If a healing arts board orders a licensee who is either in a diversion program or whose license is on probation due to a substance abuse problem to undergo a clinical diagnosis evaluation, the following applies:

1. The clinical diagnostic evaluation shall be conducted by a licensed practitioner who:

    - holds a valid, unrestricted license, which includes scope of practice to conduct a clinical diagnostic evaluation;

    - has three (3) years experience in providing evaluations of health professionals with substance abuse disorders; and,

    - is approved by the board.

2. The clinical diagnostic evaluation shall be conducted in accordance with acceptable professional standards for conducting substance abuse clinical diagnostic evaluations.

3. The clinical diagnostic evaluation report shall:

    - set forth, in the evaluator's opinion, whether the licensee has a substance abuse problem;

    - set forth, in the evaluator's opinion, whether the licensee is a threat to himself/herself or others; and,

    - set forth, in the evaluator's opinion, recommendations for substance abuse treatment, practice restrictions, or other recommendations related to the licensee's rehabilitation and safe practice.

The evaluator shall not have a financial relationship, personal relationship, or business relationship with the licensee within the last five years. The evaluator shall provide an objective, unbiased, and independent evaluation.

If the evaluator determines during the evaluation process that a licensee is a threat to himself/herself or others, the evaluator shall notify the board within 24 hours of such a determination.

For all evaluations, a final written report shall be provided to the board no later than ten (10) days from the date the evaluator is assigned the matter unless the evaluator requests additional information to complete the evaluation, not to exceed 30 days.

#2 SENATE BILL 1441 REQUIREMENT

Specific requirements for the temporary removal of the licensee from practice, in order to enable the licensee to undergo the clinical diagnostic evaluation described in subdivision (a) and any treatment recommended by the evaluator described in subdivision (a) and approved by the board, and specific criteria that the licensee must meet before being permitted to return to practice on a full-time or part-time basis.

#2 Uniform Standard

The following practice restrictions apply to each licensee who undergoes a clinical diagnostic evaluation:

1. The Board shall order the licensee to cease practice during the clinical diagnostic evaluation pending the results of the clinical diagnostic evaluation and review by the diversion program/board staff.

2. While awaiting the results of the clinical diagnostic evaluation required in Uniform Standard #1, the licensee shall be randomly drug tested at least two (2) times per week.

After reviewing the results of the clinical diagnostic evaluation, and the criteria below, a diversion or probation manager shall determine, whether or not the licensee is safe to return to either part-time or fulltime practice. However, no licensee shall be returned to practice until he or she has at least 30 days of negative drug tests.

- the license type;
- the licensee's history;
- the documented length of sobriety/time that has elapsed since substance use;
- the scope and pattern of use;
- the treatment history;
- the licensee's medical history and current medical condition;
- the nature, duration and severity of substance abuse, and
- whether the licensee is a threat to himself/herself or the public.

#3 SENATE BILL 1441 REQUIREMENT

Specific requirements that govern the ability of the licensing board to communicate with the licensee's employer about the licensee's status or condition.

#3 Uniform Standard

If the licensee who is either in a board diversion program or whose license is on probation has an employer, the licensee shall provide to the board the names, physical addresses, mailing addresses, and telephone numbers of all employers and supervisors and shall give specific, written consent that the licensee authorizes the board and the employers and supervisors to communicate regarding the licensee's work status, performance, and monitoring.

#4 SENATE BILL 1441 REQUIREMENT

Standards governing all aspects of required testing, including, but not limited to, frequency of testing, randomnicity, method of notice to the licensee, number of hours between the provision of notice and the test, standards for specimen collectors, procedures used by specimen collectors, the permissible locations of testing, whether the collection process must be observed by the collector, backup testing requirements when the licensee is on vacation or otherwise unavailable for local testing, requirements for the laboratory that analyzes the specimens, and the required maximum timeframe from the test to the receipt of the result of the test.

#4 Uniform Standard

The following drug testing standards shall apply to each licensee subject to drug testing:

1. Licensees shall be randomly drug tested at least 104 times per year for the first year and at any time as directed by the board. After the first year, licensees, who are practicing, shall be randomly drug tested at least 50 times per year, and at any time as directed by the board.

2. Drug testing may be required on any day, including weekends and holidays.

3. The scheduling of drug tests shall be done on a random basis, preferably by a computer program.

4. Licensees shall be required to make daily contact to determine if drug testing is required.

5. Licensees shall be drug tested on the date of notification as directed by the board.

6. Specimen collectors must either be certified by the Drug and Alcohol Testing Industry Association or have completed the training required to serve as a collector for the U.S. Department of Transportation.

7. Specimen collectors shall adhere to the current U.S. Department of Transportation Specimen Collection Guidelines.

8. Testing locations shall comply with the Urine Specimen Collection Guidelines published by the U.S. Department of Transportation, regardless of the type of test administered.

9. Collection of specimens shall be observed.

10. Prior to vacation or absence, alternative drug testing location(s) must be approved by the board.

11. Laboratories shall be certified and accredited by the U.S. Department of Health and Human Services.

A collection site must submit a specimen to the laboratory within one (1) business day of receipt. A chain of custody shall be used on all specimens. The laboratory shall process results and provide legally defensible test results within seven (7) days of receipt of the specimen. The appropriate board will be notified of non-negative test results within one (1) business day and will be notified of negative test results within seven (7) business days.

#5 SENATE BILL 1441 REQUIREMENT

Standards governing all aspects of group meeting attendance requirements, including, but not limited to, required qualifications for group meeting facilitators, frequency of required meeting attendance, and methods of documenting and reporting attendance or nonattendance by licensees.

#5 Uniform Standard

If a board requires a licensee to participate in group support meetings, the following shall apply:

When determining the frequency of required group meeting attendance, the board shall give consideration to the following:

- the licensee's history;
- the documented length of sobriety/time that has elapsed since substance use;
- the recommendation of the clinical evaluator;
- the scope and pattern of use;
- the licensee's treatment history; and,
- the nature, duration, and severity of substance abuse.

Group Meeting Facilitator Qualifications and Requirements:

1. The meeting facilitator must have a minimum of three (3) years experience in the treatment and rehabilitation of substance abuse, and shall be licensed or certified by the state or other nationally certified organizations.

2. The meeting facilitator must not have a financial relationship, personal relationship, or business relationship with the licensee in the last five (5) years.

3. The group meeting facilitator shall provide to the board a signed document showing the licensee's name, the group name, the date and location of the meeting, the licensee's attendance, and the licensee's level of participation and progress.

4. The facilitator shall report any unexcused absence within 24 hours**.**

#6 SENATE BILL 1441 REQUIREMENT

Standards used in determining whether inpatient, outpatient, or other type of treatment is necessary.

#6 Uniform Standard

In determining whether inpatient, outpatient, or other type of treatment is necessary, the board shall consider the following criteria:

- recommendation of the clinical diagnostic evaluation pursuant to Uniform Standard #1;
- license type;
- licensee's history;
- documented length of sobriety/time that has elapsed since substance abuse;
- scope and pattern of substance use;
- licensee's treatment history;
- licensee's medical history and current medical condition;
- nature, duration, and severity of substance abuse, and
- threat to himself/herself or the public.

#7 SENATE BILL 1441 REQUIREMENT

Worksite monitoring requirements and standards, including, but not limited to, required qualifications of worksite monitors, required methods of monitoring by worksite monitors, and required reporting by worksite monitors.

#7 Uniform Standard

A board may require the use of worksite monitors. If a board determines that a worksite monitor is necessary for a particular licensee, the worksite monitor shall meet the following requirements to be considered for approval by the board.

1. The worksite monitor shall not have financial, personal, or familial relationship with the licensee, or other relationship that could reasonably be expected to compromise the ability of the monitor to render impartial and unbiased reports to the board. If it is impractical for anyone but the licensee's employer to serve as the worksite monitor, this requirement may be waived by the board; however, under no circumstances shall a licensee's worksite monitor be an employee of the licensee.

2. The worksite monitor's license scope of practice shall include the scope of practice of the licensee that is being monitored or be another health care professional if no monitor with like practice is available.

3. The worksite monitor shall have an active unrestricted license, with no disciplinary action within the last five (5) years.

4. The worksite monitor shall sign an affirmation that he or she has reviewed the terms and conditions of the licensee's disciplinary order and/or contract and agrees to monitor the licensee as set forth by the board.

5. The worksite monitor must adhere to the following required methods of monitoring the licensee:

    a) Have face-to-face contact with the licensee in the work environment on a frequent basis as determined by the board, at least once per week.

    b) Interview other staff in the office regarding the licensee's behavior, if applicable.

    c) Review the licensee's work attendance.

Reporting by the worksite monitor to the board shall be as follows:

1. Any suspected substance abuse must be verbally reported to the board and the licensee's employer within one (1) business day of occurrence. If occurrence is not during the board's normal business hours the verbal report must be within one (1) hour of the next business day. A written report shall be submitted to the board within 48 hours of occurrence.

2. The worksite monitor shall complete and submit a written report monthly or as directed by the board. The report shall include:

    - the licensee's name;
    - license number;
    - worksite monitor's name and signature;
    - worksite monitor's license number;
    - worksite location(s);
    - dates licensee had face-to-face contact with monitor;
    - staff interviewed, if applicable;
    - attendance report;
    - any change in behavior and/or personal habits;
    - any indicators that can lead to suspected substance abuse.

The licensee shall complete the required consent forms and sign an agreement with the worksite monitor and the board to allow the board to communicate with the worksite monitor.

#8 SENATE BILL 1441 REQUIREMENT

Procedures to be followed when a licensee tests positive for a banned substance.

#8 Uniform Standard

When a licensee tests positive for a banned substance:

1. The board shall order the licensee to cease practice;

2. The board shall contact the licensee and instruct the licensee to leave work; and

3. The board shall notify the licensee's employer, if any, and worksite monitor, if any, that the licensee may not work.

Thereafter, the board should determine whether the positive drug test is in fact evidence of prohibited use. If so, proceed to Standard #9. If not, the board shall immediately lift the cease practice order.

In determining whether the positive test is evidence of prohibited use, the board should, as applicable:

1. Consult the specimen collector and the laboratory;

2. Communicate with the licensee and/or any physician who is treating the licensee; and

3. Communicate with any treatment provider, including group facilitator/s.

#9 SENATE BILL 1441 REQUIREMENT

Procedures to be followed when a licensee is confirmed to have ingested a banned substance.

#9 Uniform Standard

When a board confirms that a positive drug test is evidence of use of a prohibited substance, the licensee has committed a major violation, as defined in Uniform Standard #10 and the board shall impose the consequences set forth in Uniform Standard #10.

#10 SENATE BILL 1441 REQUIREMENT

Specific consequences for major and minor violations. In particular, the committee shall consider the use of a "deferred prosecution" stipulation described in Section 1000 of the Penal Code, in which the licensee admits to self-abuse of drugs or alcohol and surrenders his or her license. That agreement is deferred by the agency until or unless licensee commits a major violation, in which case it is revived and license is surrendered.

#10 Uniform Standard

Major Violations include, but are not limited to:

1. Failure to complete a board-ordered program;
2. Failure to undergo a required clinical diagnostic evaluation;
3. Multiple minor violations;
4. Treating patients while under the influence of drugs/alcohol;
5. Any drug/alcohol related act which would constitute a violation of the practice act or state/federal laws;
6. Failure to obtain biological testing for substance abuse;
7. Testing positive and confirmation for substance abuse pursuant to Uniform Standard #9;
8. Knowingly using, making, altering or possessing any object or product in such a way as to defraud a drug test designed to detect the presence of alcohol or a controlled substance.

Consequences for a major violation include, but are not limited to:

1. Licensee will be ordered to cease practice.
    a) the licensee must undergo a new clinical diagnostic evaluation, and
    b) the licensee must test negative for at least a month of continuous drug testing before being allowed to go back to work.
2. Termination of a contract/agreement.
3. Referral for disciplinary action, such as suspension, revocation, or other action as determined by the board.

Minor Violations include, but are not limited to:

1. Untimely receipt of required documentation;
2. Unexcused non-attendance at group meetings;
3. Failure to contact a monitor when required;
4. Any other violations that do not present an immediate threat to the violator or to the public.

Consequences for minor violations include, but are not limited to**:**

1. Removal from practice;
2. Practice limitations;
3. Required supervision;
4. Increased documentation;
5. Issuance of citation and fine or a warning notice;
6. Required re-evaluation/testing;
7. Other action as determined by the board.

#11 SENATE BILL 1441 REQUIREMENT

Criteria that a licensee must meet in order to petition for return to practice on a full time basis.

#11 Uniform Standard

"Petition" as used in this standard is an informal request as opposed to a "Petition for Modification" under the Administrative Procedure Act.

The licensee shall meet the following criteria before submitting a request (petition) to return to full time practice:

1. Demonstrated sustained compliance with current recovery program.

2. Demonstrated the ability to practice safely as evidenced by current work site reports, evaluations, and any other information relating to the licensee's substance abuse.

3. Negative drug screening reports for at least six (6) months, two (2) positive worksite monitor reports, and complete compliance with other terms and conditions of the program.

#12 SENATE BILL 1441 REQUIREMENT

Criteria that a licensee must meet in order to petition for reinstatement of a full and unrestricted license.

#12 Uniform Standard

"Petition for Reinstatement" as used in this standard is an informal request (petition) as opposed to a "Petition for Reinstatement" under the Administrative Procedure Act.

The licensee must meet the following criteria to request (petition) for a full and unrestricted license.

1. Demonstrated sustained compliance with the terms of the disciplinary order, if applicable.

2. Demonstrated successful completion of recovery program, if required.

3. Demonstrated a consistent and sustained participation in activities that promote and support their recovery including, but not limited to, ongoing support meetings, therapy, counseling, relapse prevention plan, and community activities.

4. Demonstrated that he or she is able to practice safely.

5. Continuous sobriety for three (3) to five (5) year.

#13 SENATE BILL 1441 REQUIREMENT

If a board uses a private-sector vendor that provides diversion services, (1) standards for immediate reporting by the vendor to the board of any and all noncompliance with process for providers or contractors that provide diversion services, including, but not limited to, specimen collectors, group meeting facilitators, and worksite monitors; (3) standards requiring the vendor to disapprove and discontinue the use of providers or contractors that fail to provide effective or timely diversion services; and (4) standards for a licensee's termination from the program and referral to enforcement.

#13 Uniform Standard

1. A vendor must report to the board any major violation, as defined in Uniform Standard #10, within one (1) business day. A vendor must report to the board any minor violation, as defined in Uniform Standard #10, within five (5) business days.

2. A vendor's approval process for providers or contractors that provide diversion services, including, but not limited to, specimen collectors, group meeting facilitators, and worksite monitors is as follows:

   Specimen Collectors:

   a) The provider or subcontractor shall possess all the materials, equipment, and technical expertise necessary in order to test every licensee for which he or she is responsible on any day of the week.

   b) The provider or subcontractor shall be able to scientifically test for urine, blood, and hair specimens for the detection of alcohol, illegal, and controlled substances.

   c) The provider or subcontractor must provide collection sites that are located in areas throughout California.

   d) The provider or subcontractor must have an automated 24-hour toll-free telephone system and/or a secure on-line computer database that allows the participant to check in daily for drug testing.

   e) The provider or subcontractor must have or be subcontracted with operating collection sites that are engaged in the business of collecting urine, blood, and hair follicle specimens for the testing of drugs and alcohol within the State of California.

   f) The provider or subcontractor must have a secure, HIPAA compliant, website or computer system to allow staff access to drug test results and compliance reporting information that is available 24 hours a day.

g) The provider or subcontractor shall employ or contract with toxicologists that are licensed physicians and have knowledge of substance abuse disorders and the appropriate medical training to interpret and evaluate laboratory drug test results, medical histories, and any other information relevant to biomedical information.

h) A toxicology screen will not be considered negative if a positive result is obtained while practicing, even if the practitioner holds a valid prescription for the substance.

i) Must undergo training as specified in Uniform Standard #4 (6).

Group Meeting Facilitators:

A group meeting facilitator for any support group meeting:

a) must have a minimum of three (3) years experience in the treatment and rehabilitation of substance abuse;

b) must be licensed or certified by the state or other nationally certified organization;

c) must not have a financial relationship, personal relationship, or business relationship with the licensee in the last five (5) years;

d) shall report any unexcused absence within 24 hours to the board, and,

e) shall provide to the board a signed document showing the licensee's name, the group name, the date and location of the meeting, the licensee's attendance, and the licensee's level of participation and progress.

Work Site Monitors:

1. The worksite monitor must meet the following qualifications:

   a) Shall not have financial, personal, or familial relationship with the licensee, or other relationship that could reasonably be expected to compromise the ability of the monitor to render impartial and unbiased reports to the board. If it is impractical for anyone but the licensee's employer to serve as the worksite monitor, this requirement may be waived by the board; however, under no circumstances shall a licensee's worksite monitor be an employee of the licensee.

   b) The monitor's licensure scope of practice shall include the scope of practice of the licensee that is being monitored or be another health care professional, if no monitor with like practice is available.

   c) Shall have an active unrestricted license, with no disciplinary action within the last five (5) years.

d) Shall sign an affirmation that he or she has reviewed the terms and conditions of the licensee's disciplinary order and/or contract and agrees to monitor the licensee as set forth by the board.

2. The worksite monitor must adhere to the following required methods of monitoring the licensee:

   a) Have face-to-face contact with the licensee in the work environment on a frequent basis as determined by the board, at least once per week.

   b) Interview other staff in the office regarding the licensee's behavior, if applicable.

   c) Review the licensee's work attendance.

3. Any suspected substance abuse must be verbally reported to the contractor, the board, and the licensee's employer within one (1) business day of occurrence. If occurrence is not during the board's normal business hours the verbal report must be within one (1) hour of the next business day. A written report shall be submitted to the board within 48 hours of occurrence.

4. The worksite monitor shall complete and submit a written report monthly or as directed by the board. The report shall include:

   - the licensee's name;
   - license number;
   - worksite monitor's name and signature;
   - worksite monitor's license number;
   - worksite location(s);
   - dates licensee had face-to-face contact with monitor;
   - staff interviewed, if applicable;
   - attendance report;
   - any change in behavior and/or personal habits;
   - any indicators that can lead to suspected substance abuse.

<u>Treatment Providers</u>

1. Treatment facility staff and services must have:

   a) Licensure and/or accreditation by appropriate regulatory agencies;

   b) Sufficient resources available to adequately evaluate the physical and mental needs of the client, provide for safe detoxification, and manage any medical emergency;

   c) Professional staff who are competent and experienced members of the clinical staff;

d) Treatment planning involving a multidisciplinary approach and specific aftercare plans;

e) Means to provide treatment/progress documentation to the provider.

2. The vendor shall disapprove and discontinue the use of providers or contractors that fail to provide effective or timely diversion services as follows:

a) The vendor is fully responsible for the acts and omissions of its subcontractors and of persons either directly or indirectly employed by any of them. No subcontract shall relieve the vendor of its responsibilities and obligations All state policies, guidelines, and requirements apply to all subcontractors.

b) If a subcontractor fails to provide effective or timely services as listed above, but not limited to any other subcontracted services, the vendor will terminate services of said contractor within 30 business days of notification of failure to provide adequate services.

c) The vendor shall notify the appropriate board within five (5) business days of termination of said subcontractor.

#14 SENATE BILL 1441 REQUIREMENT

If a board uses a private-sector vendor that provides diversion services, the extent to which licensee participation in that program shall be kept confidential from the public.

#14 Uniform Standard

The board shall disclose the following information to the public for licensees who are participating in a board monitoring/diversion program regardless of whether the licensee is a self-referral or a board referral. However, the disclosure shall not contain information that the restrictions are a result of the licensee's participation in a diversion program.

- Licensee's name;
- Whether the licensee's practice is restricted, or the license is on inactive status;
- A detailed description of any restriction imposed.

#15 SENATE BILL 1441 REQUIREMENT

If a board uses a private-sector vendor that provides diversion services, a schedule for external independent audits of the vendor's performance in adhering to the standards adopted by the committee.

#15 Uniform Standard

1. If a board uses a private-sector vendor to provide monitoring services for its licensees, an external independent audit must be conducted at least once every three (3) years by a qualified, independent reviewer or review team from outside the department with no real or apparent conflict of interest with the vendor providing the monitoring services. In addition, the reviewer shall not be a part of or under the control of the board. The independent reviewer or review team must consist of individuals who are competent in the professional practice of internal auditing and assessment processes and qualified to perform audits of monitoring programs.

2. The audit must assess the vendor's performance in adhering to the uniform standards established by the board. The reviewer must provide a report of their findings to the board by June 30 of each three (3) year cycle. The report shall identify any material inadequacies, deficiencies, irregularities, or other non-compliance with the terms of the vendor's monitoring services that would interfere with the board's mandate of public protection.

3. The board and the department shall respond to the findings in the audit report.

#16 SENATE BILL 1441 Requirement

Measurable criteria and standards to determine whether each board's method of dealing with substance-abusing licensees protects patients from harm and is effective in assisting its licensees in recovering from substance abuse in the long term.

#16 Uniform Standard

Each board shall report the following information on a yearly basis to the Department of Consumer Affairs and the Legislature as it relates to licensees with substance abuse problems who are either in a board probation and/or diversion program.

- Number of intakes into a diversion program
- Number of probationers whose conduct was related to a substance abuse problem
- Number of referrals for treatment programs
- Number of relapses (break in sobriety)
- Number of cease practice orders/license in-activations
- Number of suspensions
- Number terminated from program for noncompliance
- Number of successful completions based on uniform standards
- Number of major violations; nature of violation and action taken
- Number of licensees who successfully returned to practice
- Number of patients harmed while in diversion

The above information shall be further broken down for each licensing category, specific substance abuse problem (i.e. cocaine, alcohol, Demerol etc.), whether the licensee is in a diversion program and/or probation program.

If the data indicates that licensees in specific licensing categories or with specific substance abuse problems have either a higher or lower probability of success, that information shall be taken into account when determining the success of a program. It may also be used to determine the risk factor when a board is determining whether a license should be revoked or placed on probation.

The board shall use the following criteria to determine if its program protects patients from harm and is effective in assisting its licensees in recovering from substance abuse in the long term.

- At least 100 percent of licensees who either entered a diversion program or whose license was placed on probation as a result of a substance abuse problem successfully completed either the program or the probation, or had their license to practice revoked or surrendered on a timely basis based on noncompliance of those programs.

- At least 75 percent of licensees who successfully completed a diversion program or probation did not have any substantiated complaints related to substance abuse for at least five (5) years after completion.

Attachment 4

EFFECTS ALL INDIVIDUAL LICENSE TYPES

4. Cooperate with Board Staff

Respondent shall timely cooperate with the board's inspection program and with the board's monitoring and investigation of respondent's compliance with the terms and conditions of his or her probation, including but not limited to: timely responses to requests for information by board staff; timely compliance with directives from board staff regarding requirements of any term or condition or probation; and timely completion of documentation pertaining to a term or condition of probation. Failure to cooperate shall be considered a violation of probation.

5. Continuing Education

Respondent shall provide evidence of efforts to maintain skill and knowledge as a ~~pharmacist~~ [fill in license type] as directed by the board or its designee.

6. Notice to Employers

During the period of probation, respondent shall notify all present and prospective employers of the decision in case number _____ and the terms, conditions and restrictions imposed on respondent by the decision, as follows:

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment, respondent shall cause (a) his or her direct supervisor, (b) his or her pharmacist-in-charge, designated representative-in-charge, or other compliance supervisor ~~(including each new pharmacist-in-charge employed during respondent's tenure of employment)~~ and (c) the owner or owner representative of his or her employer, to report to the board in writing acknowledging that the listed individual(s) has/have read the decision in case number _____, and terms and conditions imposed thereby. If one person serves in more than one role described in (a), (b), or (c) during the term of probation, respondent shall cause the person(s) taking over the role(s) to report to the board in writing within fifteen (15) days of the change acknowledging that he or she has read the decision in case number _____, and the terms and conditions imposed thereby. ~~It shall be respondent's responsibility to ensure that his or her employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.~~

If respondent works for or is employed by or through ~~a pharmacy~~an employment service, respondent must notify the person(s) described in (a), (b), and (c) above at every entity licensed by the board of the decision in case number _____, and the terms and conditions imposed thereby in advance of respondent commencing work at such licensed entity ~~his or her direct supervisor, pharmacist-in-charge, and owner at every entity licensed by the board of the terms and conditions of the decision in case number _____ in advance of the respondent commencing work at each licensed entity.~~ A record of this notification must be provided to the board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment by or through ~~a pharmacy~~an employment service, respondent shall cause the person(s) described in (a), (b), and (c) ~~his or her direct supervisor with the pharmacy~~at the employment service to report to the board in writing acknowledging that he or she has read the decision in case number _____ and the terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that these acknowledgment(s) are timely submitted to the board~~his or her employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board~~.

Failure to timely notify present or prospective employer(s) or failure to cause the identified person(s) with that/those employer(s) to submit timely written acknowledgments to the board shall be considered a violation of probation.

> "Employment" within the meaning of this provision ~~shall~~ includes any full-time, part-time, temporary, relief, or employment/ ~~or pharmacy~~ management service position as a _____ ~~pharmacist~~ or any position for which a _____ ~~pharmacist~~ license is a requirement or criterion for employment, whether the respondent is an employee, independent contractor or volunteer.

12. Notification of a Change(s) in Name, Employment, ~~Residence~~ Address(es), or Phone Number(s) ~~Mailing Address or Employment~~

Respondent shall notify the board in writing within ten (10) days of any change of employment. Said notification shall include the reasons for leaving, the address of the new employer, the name of the supervisor and owner, and the work schedule if known. Respondent shall further notify the board in writing within ten (10) days of a change in name, residence address, mailing address, or phone number(s).

Failure to timely notify the board of any change in employer(s), name(s), address(es), or phone number(s) shall be considered a violation of probation.

13. ~~Tolling of Probation~~License Practice Requirement - Tolling

Except during periods of suspension, respondent shall, at all times while on probation, be employed as a ~~pharmacist~~ _____ in California for a minimum of _____ hours per calendar month. Any month during which this minimum is not met shall toll the period of probation, i.e., the period of probation shall be extended by one month for each month during which this minimum is not met. During any such period of tolling of probation, respondent must nonetheless comply with all terms and conditions of probation, unless the respondent is informed otherwise in writing by the board or its designee.

~~Should respondent, regardless of residency, for any reason (including vacation) cease practicing as a pharmacist for a minimum of _____ hours per calendar month in California,~~If respondent does not practice as a _____ in California for a minimum of _____ hours in any calendar month, for any reason (including vacation), respondent must notify the board in writing within ten (10) days

of the ~~cessation~~ conclusion of that calendar month. This notification shall include at least the date(s), locations(s), and hours of practice; the reason(s) for the interruption or decline in practice; and the anticipated date(s) on which respondent will resume practice at the required level. Respondent shall further notify the board in writing within ten (10) days following the next calendar month during which respondent practices as a _____ in California for a minimum of _____ hours. ~~of practice, and must further notify the board in writing within ten (10) days of the resumption of practice.~~ Any failure to timely provide such notification(s) shall be considered a violation of probation.

It is a violation of probation for respondent's probation to remain tolled pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding thirty-six (36) months.

> ~~"Cessation of practice" means any calendar month during which respondent is not practicing as a pharmacist for at least _____ hours, as defined by Business and Professions Code section 4000 et seq . "Resumption of practice" means any calendar month during which respondent is practicing as a pharmacist for at least _____ hours as a pharmacist as defined by Business and Professions Code section 4000 et seq.~~

Option #1: As a condition precedent to successful completion of probation, during the period of probation respondent shall practice as a _____ in a licensed _____ in California [that dispenses dangerous drugs] for a minimum of one (1) year. [After the first year or probation, the board or its designee may consider a modification of this requirement.] Failure to comply with this requirement (or as modified) shall be considered a violation of probation. ~~Respondent is required to practice as a pharmacist in a licensed pharmacy setting that dispenses medication for a minimum of one year prior to the completion of probation. After the first year of probation, the board or its designee may consider a modification of this requirement. If respondent fails to comply with this requirement or a subsequent modification thereto, such failure shall be considered a violation of probation.~~

Option #2: Respondent shall remain open and engaged in its ordinary business as a _____ in California for a minimum of _____hours per calendar month. Any month during which this minimum is not met shall toll the period of probation, i.e., the period of probation shall be extended by one month for each month during which this minimum is not met. During any such period of tolling of probation, respondent must nonetheless comply with all terms and conditions of probation, unless respondent is informed otherwise in writing by the board or its designee. If respondent is not open and engaged in its ordinary business as a _____ in California for a minimum of _____ hours in any calendar month, for any reason (including vacation), respondent shall notify the board in writing within ten (10) days of the conclusion of that calendar month. This notification shall include at least: the date(s) and hours respondent was last open; the reason(s) for the interruption or decline in practice; and the anticipated date(s) on which respondent will resume at the required level. Respondent shall further notify the board in writing within ten (10) days following the next calendar month during which respondent is open and engaged in its ordinary business as a _____ in California for a minimum of

_____ hours. Any failure to timely provide such notification(s) shall be considered a violation of probation.

Option #3: [For a first-year pharmacist intern] During respondent's first academic year of enrollment in a school or college of pharmacy, no minimum practice hours shall be required. Instead, respondent shall report to the board quarterly in writing, in a format and schedule as directed by the board or its designee, on [his/her] academic progress. This exemption shall apply only once, and only during respondent's first academic year. Respondent must comply with all other terms and conditions of probation, unless informed otherwise in writing by the board or its designee.

18. Mental Health Examination (Appropriate for those cases where evidence demonstrates that mental illness, substance abuse or disability was a contributing cause of the violations.)

Within thirty (30) days of the effective date of this decision, and on a periodic basis as may be required by the board or its designee, respondent shall undergo, at his or her own expense, psychiatric evaluation(s) by a board-appointed or board-approved licensed mental health practitioner. The approved evaluator shall be provided with a copy of the board's [accusation or petition to revoke probation] and decision. Respondent shall sign a release authorizing the evaluator to furnish the board with a current diagnosis and a written report regarding the respondent's judgment and ability to function independently as a pharmacist with safety to the public. Respondent shall comply with all the recommendations of the evaluator if directed by the board or its designee, included but not limited, psychotherapy or other terms and conditions listed in the board's disciplinary guidelines.

~~If the evaluator recommends, and the board or its designee directs, respondent shall undergo psychotherapy. Within thirty (30) days of notification by the board that a recommendation for psychotherapy has been accepted, respondent shall submit to the board or its designee, for prior approval, the name and qualification of a licensed mental health practitioner of respondent's choice. Within thirty (30) days of approval thereof by the board, respondent shall submit documentation to the board demonstrating the commencement of psychotherapy with the approved licensed mental health practitioner. Should respondent, for any reason, cease treatment with the approved licensed mental health practitioner, respondent shall notify the board immediately and, within thirty (30) days of ceasing treatment therewith, submit the name of a replacement licensed mental health practitioner of respondent's choice to the board for its prior approval. Within thirty (30) days of approval thereof, respondent shall submit documentation to the board demonstrating the commencement of psychotherapy with the approved replacement. Failure to comply with any requirement or deadline stated by this paragraph shall be considered a violation of probation.~~

~~Upon approval of the initial or any subsequent licensed mental health practitioner, respondent shall undergo and continue treatment with that therapist, at respondent's own expense, until the therapist recommends in writing to the board, and the board or its designee agrees by way of a written notification to respondent, that no further~~

~~psychotherapy is necessary. Upon receipt of such recommendation from the treating therapist, and before determining whether to accept or reject said recommendation, the board or its designee may require respondent to undergo, at respondent's expense, a mental health evaluation by a separate board-appointed or board-approved evaluator. If the approved evaluator recommends that respondent continue psychotherapy, the board or its designee may require respondent to continue psychotherapy.~~

~~Psychotherapy shall be at least once a week unless otherwise approved by the board. Respondent shall provide the therapist with a copy of the board's [accusation or petition to revoke probation] and decision no later than the first therapy session. Respondent shall take all necessary steps to ensure that the treating therapist submits written quarterly reports to the board concerning respondent's fitness to practice, progress in treatment, and other such information as may be required by the board or its designee.~~

If at any time the approved evaluator ~~or therapist~~ determines that respondent is unable to practice safely or independently as a pharmacist, the evaluator ~~licensed mental health practitioner~~ shall notify the board immediately by telephone and follow up by written letter within three (3) working days. Upon notification from the board or its designee of this determination, respondent shall be automatically suspended and shall not resume practice until notified by the board that practice may be resumed.

Option #1: Commencing on the effective date of this decision, respondent shall not engage in the practice of _____ until notified in writing by the board that respondent has been deemed psychologically fit to practice _____ safely, and the board or its designee approves said recommendation.

During any such suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and controlled substances. Respondent shall not resume practice until notified by the board.

During any such suspension, respondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

Failure to comply with ~~this~~any such suspension shall be considered a violation of probation.

(Option language to be used in addition to standard language)
Option #2: If recommended by the evaluating licensed mental health practitioner and approved by the board, respondent shall be suspended from the practice of _____ until respondent's treating therapist recommends, in writing, stating the basis therefore, that respondent can safely practice pharmacy, and the board or its designee approves said recommendation.

During any such suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and controlled substances. Respondent shall not resume practice until notified by the board.

During any such suspension, respondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

Failure to comply with ~~this~~any such suspension shall be considered a violation of probation.

Uniform Standard 1
(Appropriate for those cases where evidence demonstrates substance abuse was a cause of the violations. May be appropriate to use in conjunction with option 2)

Option #3: In approving a licensed mental health practitioner, the board shall ensure that the evaluate holds an unrestricted license which includes a scope of practice to conduct a clinical diagnostic evaluation and has three years of experience in providing evaluation to health professional with substance abuse disorders. The evaluation shall not have a financial, personal or business relationship within the last five years.

The evaluate shall be conducted in accordance with acceptable professional standards for conducting substance abuse clinical diagnostic evaluation and shall include the evaluator's opinion whether the licensee has a substance abuse problem, whether the licensee is a threat to himself/herself or others and

recommendations for substance abuse treatment, practice restrictions or other recommendations related to the licensee's rehabilitation and safe practice.

(Uniform Standard 4)

22. Random Drug Screening (If PRP provision is required, this term is also to be included to allow for continued fluid monitoring by the Board in cases where a respondent successfully completes the PRP before completion of the probation period; terms is also appropriate for those cases where the evidence demonstrates that the respondent may have a problem with chemical dependency (drugs, alcohol) but where the PRP is not required.)

Respondent, at his or her own expense, shall participate in random testing, including but not limited to biological fluid testing (urine, blood), breathalyzer, hair follicle testing, or other drug screening program as directed by the board or its designee. Respondent shall be required to make daily contact to determine if drug testing is required. Respondent shall be drug tested on the date of notification and the collection of specimens shall be observed. Respondent may be required to participate in testing for the entire probation period and the frequency of testing will be determined by the board or its designee. At all times, respondent shall fully cooperate with the board or its designee, and shall, when directed, submit to such tests and samples for the detection of alcohol, narcotics, hypnotics, dangerous drugs or other controlled substances as the board or its designee may direct. Failure to timely submit to testing as directed shall be considered a violation of probation. Respondent shall provide to the board a copy of any prescription issued by a prescriber within 24 hours of the prescription being dispensed or administered. Upon request of the board or its designee, respondent shall provide documentation from ~~a~~ the prescriber licensed practitioner that the prescription ~~for a detected drug~~ was legitimately issued and is a necessary part of the treatment of the respondent. Failure to timely provide such documentation shall be considered a violation of probation. Any confirmed positive test for alcohol or for any drug not lawfully prescribed by a licensed practitioner as part of a documented medical treatment shall be considered a violation of probation and shall result in the automatic suspension of practice of pharmacy by respondent. Respondent may not resume the practice of pharmacy until notified by the board in writing.

During any such suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and controlled substances. Respondent shall not resume practice until notified by the board.

During any such suspension, respondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the

duties of a pharmacy technician or a designated representative for any entity licensed by the board.

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

Failure to comply with ~~this~~any such suspension shall be considered a violation of probation.

25. Community Services Program

Within sixty (60) days of the effective date of this decision, respondent shall submit to the board or its designee, for prior approval, a community service program in which respondent shall provide free health-care related services on a regular basis to a community or charitable facility or agency for at least _____ hours per _____ for the first _____ of probation. Within thirty (30) days of board approval thereof, respondent shall submit documentation to the board demonstrating commencement of the community service program. ~~A record of this notification must be provided to the board upon request.~~ Respondent shall report on progress with the community service program in the quarterly reports. Failure to timely submit, commence, or comply with the program shall be considered a violation of probation.

~~**28. Pharmacy Self-Assessment Mechanism**~~

~~Within the first year of probation, respondent shall complete the Pharmacist Self-Assessment Mechanism (PSAM) examination provided by the National Association of Boards of Pharmacy (NABP). Respondent shall submit a record of completion to the board demonstrating he/she has completed this examination. Respondent shall bear all costs for the examination. Continuing education hours received for this examination shall not be used as part of the required continuing education hours for renewal purposes.~~

~~Failure to timely complete the PSAM or submit documentation thereof shall be considered a violation of probation.~~

~~**Option A:** Respondent shall waive any rights to confidentiality and provide examination results to the board or its designee.~~

~~**Option B:** (This term must be accompanied by the "Remedial Education" term. [Include/Modify Remedial Education Term to Conform].) Respondent shall waive any rights to confidentiality and provide examination results to the board or its designee. Based on the results of the examination, the board shall determine which courses are appropriate for remedial education.~~

32. No Ownership or Management of Licensed Premises

Respondent shall not own, have any legal or beneficial interest in, ~~or~~ nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board. Respondent shall sell or transfer any legal or beneficial interest in any entity licensed by the board within ninety (90) days following the effective date of this decision and shall immediately thereafter provide written proof thereof to the board. Failure to timely divest any legal or beneficial interest(s) or provide documentation thereof shall be considered a violation of probation.

33. Separate File of Controlled Substances Records (For pharmacist owners and pharmacists-in-charge)

Respondent shall maintain and make available for inspection a separate file of all records pertaining to the acquisition or disposition of all controlled substances. Failure to maintain such file or make it available for inspection shall be considered a violation of probation.

34. Report of Controlled Substances ~~(For pharmacist owners and pharmacists-in-charge)~~

Respondent shall submit quarterly reports to the board detailing the total acquisition and disposition of such controlled substances as the board or its designee may direct. Respondent shall specify the manner of disposition (e.g., by prescription, due to burglary, etc.) or acquisition (e.g., from a manufacturer, from another retailer, etc.) of such controlled substances. Respondent shall report on a quarterly basis or as directed by the board. The report shall be delivered or mailed to the board no later than ten (10) days following the end of the reporting period determined by the board or its designee. Failure to timely prepare or submit such reports shall be considered a violation of probation.

39. Surrender of DEA Permit

Within thirty (30) days of the effective date of this decision, respondent shall surrender his or her federal Drug Enforcement Administration (DEA) permit to the DEA, for cancellation. Respondent shall provide documentary proof of such cancellation to the board or its designee. Respondent is prohibited from ~~prescribing~~ dispensing, furnishing, or otherwise providing dangerous drugs or controlled substances until the board has received satisfactory proof of cancellation. Thereafter, respondent shall not apply/reapply for a DEA registration number without the prior written consent of the board or its designee.

Option: Respondent may obtain a DEA permit restricted to Schedule(s) _____ controlled substance(s).

Option: Respondent shall not order, receive, or retain any federal order forms, including 222 forms, for controlled substances.

SPECIFIC TO INTERN PHARMACISTS AND PHARMACISTS ONLY

21. Pharmacists Recovery Program (PRP) (Appropriate for chemical dependency (alcohol, drugs), or psychiatric disorders (mental illness, emotional disturbance, gambling.)

Within ~~thirty (30)~~ ten (10) days of the effective date of this decision, the respondent shall have completed the following: contacted the Pharmacists Recovery Program (PRP) ~~for evaluation,~~ and completed an intake with a clinical case manager, successfully completed registration for any drug or alcohol testing mandated by the PRP and begun compliance with the drug or alcohol testing protocol(s) and other treatment contract requirements. Respondent shall immediately thereafter enroll~~,~~ and shall successfully participate in~~,~~ the PRP and complete the treatment contract and any ~~subsequent~~ addendums ~~as recommended and provided by the PRP and as~~ required or suggested by the PRP and approved by the board or its designee. The costs for PRP participation shall be borne by the respondent.

If respondent is currently enrolled in the PRP, said participation is now mandatory and as of the effective date of this decision is no longer considered a self-referral under Business and Professions Code section 4362(c)(2). Respondent shall successfully participate in and complete his or her current contract and any subsequent addendums with the PRP.

Failure to timely contact or enroll in the PRP, complete the treatment contract and any addendums, complete testing registration, comply with testing, and/or successfully participate in and complete the treatment contract and/or any addendums, shall be considered a violation of probation.

Probation shall be automatically extended until respondent successfully completes the PRP. Any person terminated from the PRP program shall be automatically suspended by the board. Respondent may not resume the practice of pharmacy until notified by the board in writing.

Any confirmed positive test for alcohol or for any drug not lawfully prescribed by a licensed practitioner as part of a documented medical treatment shall result in the automatic suspension of practice by respondent and shall be considered a violation of probation. Respondent may not resume the practice of pharmacy until notified by the board in writing.

During any such suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of

dangerous drugs and controlled substances. Respondent shall not resume practice until notified by the board.

During any such suspension, respondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

Failure to comply with ~~this~~ any such suspension shall be considered a violation of probation.

Respondent shall pay administrative fees as invoiced by the PRP or its designee. Fees not timely paid to the PRP shall constitute a violation for probation. The board will collect unpaid administrative fees as part of the annual probation monitoring costs if not submitted to the PRP.

(Option language to be used in ~~addition to~~conjuction with standard language)
Option: Respondent shall work in a pharmacy setting with access to controlled substances for six (6) consecutive months before successfully completing probation. If respondent fails to do so, probation shall be automatically extended until this condition has been met. Failure to satisfy this condition within six (6) months beyond the original date of expiration of the term of probation shall be considered a violation of probation.

SPECIFIC TO PHARMACY TECHNICIANS AND DESIGNATED REPRESENTATIVES LICENSES ONLY

16. **Attend ~~Substance Abuse~~ Recovery ~~Relapse Prevention and Support~~ Group(s)** (Appropriate for those cases with chemical dependency (alcohol, drugs))

Within thirty (30) days of the effective date of this decision, respondent shall begin regular attendance at a recognized and established substance abuse recovery support group in California, (e.g., Alcoholics Anonymous, Narcotics Anonymous, etc.) which has been approved by the board or its designee. Respondent must attend at least one group meeting per week unless otherwise directed by the board or its designee. Respondent shall continue regular attendance and submit signed and dated documentation confirming attendance with each quarterly report for the duration of probation. Failure to attend or submit documentation thereof shall be considered a violation of probation.

(Uniform Standard 7)

18. **Work Site Monitor** (Appropriate for those cases with chemical dependency (alcohol, drugs where the respondent is not required to participate in the PRP))

Within ten (10) days of the effective date of this decision, respondent shall identify a work site monitor, for prior approval by the board, who shall be responsible for supervising respondent during working hours. Respondent shall provide the proposed work site monitor with a copy of the pleading document and the disciplinary order. In approving a work site monitor, the board or its designee shall consider if the proposed monitor has a financial, personal or familial relationship with the respondent that could reasonably be expected to compromise the ability of the monitor to render impartial or unbiased reports to the board. The board shall also confirm that the proposed worksite monitor shall have an active, unrestricted license, with no disciplinary action within the last five (5) years. Upon approval of a work site monitor, the approved monitor shall provide the board with a signed affirmation indicating their review and understanding of the discipline imposed and their agreement to monitor the licensee. Further, respondent shall complete a consent form and sign an agreement with the worksite monitor allowing the board and worksite monitor to communicate.

Respondent shall be responsible for ensuring that the work site monitor reports in writing to the board ~~quarterly~~ monthly. The report shall be made on a form approved by the board and shall include the respondent's name, license number, worksite monitor's name and license number, the work location(s), dates of face-to-face contact, staff interviewed, if applicable; attendance reports as well as any notations documenting changes in behavior and/or personal habits or any indications that can lead to suspected substance abuse. Should the designated work site monitor determine at any time during the probationary period that respondent has not maintained sobriety, he or she shall immediately notify the board verbally or by other

electronic means and shall submit a written report to the board within 48 hours of occurrence ~~immediately, either orally or in writing as directed~~.

Should respondent change employment or require a replacement work site monitor, a new work site monitor must be designated, for prior approval by the board, within ten (10) days of proposed change ~~commencing new employment~~.

Failure to identify an acceptable initial or replacement work site monitor, or to ensure ~~quarterly~~ monthly reports are submitted to the board, shall be considered a violation of probation.

SPECIFIC TO SITE LICENSES ONLY

11. Posted Notice of Probation

Respondent owner shall prominently post a probation notice provided by the board or its designee in a place conspicuous and readable to the public within two (2) days of receipt thereof from the board or its designee. Failure to timely post such notice, or to maintain the posting during the entire period of probation, shall be considered a violation of probation. ~~The probation notice shall remain posted during the entire period of probation.~~

Respondent owner shall not, directly or indirectly, engage in any conduct or make any statement which is intended to mislead or is likely to have the effect of misleading any patient, customer, member of the public, or other person(s) as to the nature of and reason for the probation of the licensed entity.

~~Failure to post such notice shall be considered a violation of probation.~~

19. Posted Notice of Suspension

Respondent owner shall prominently post a suspension notice provided by the board or its designee in a place conspicuous and readable to the public within two (2) days of the receipt thereof from the board or its designee. Failure to timely post such notice, or to maintain the posting during the entire period of suspension, shall be considered a violation of probation. ~~The suspension notice shall remain posted during the entire period of suspension ordered by this decision.~~

Respondent owner shall not, directly or indirectly, engage in any conduct or make any statement, orally, electronically or in writing, which is intended to mislead or is likely to have the effect of misleading any patient, customer, member of the public, or other person(s) as to the nature of and reason for the closure of the licensed entity.

Attachment 5

Compounding Questions and Answers, January 10, 2011

1. Question: **What is a "reliable supplier?"**

Answer: Some examples of reliable suppliers are FDA licensed manufacturers, CA Department of Public Health – Food and Drug Branch licensed drug repackagers; CA licensed pharmacies and wholesalers; CA licensed non-resident wholesalers.

Prior to making a purchase, it is recommended to check the board's website – www.pharmacy.ca.gov -. to verify if the wholesaler or non-resident pharmacy is licensed by the board.

If purchasing chemicals from another country, obtain a certificate issued by the FDA authorizing shipment of the product into the U.S. and a certificate of analysis printed in English.

As a reminder, any pharmacy purchasing, trading, selling, or transferring drugs to an entity not licensed by the board could be cited and fined up to $5000 per transaction

Reference: B&P §§ 4160, 4163, 4126.5, 4169(a)(1); CCR §§ 1780, 1783, 1735.3(c)

2. Question: **Do cytotoxic agents and other hazardous substances have the same requirements for qualitative and quantitative analysis?**

Answer: Yes

3. Question: **Is a non-resident pharmacy (NRP) that provides compounded product into CA required to meet the same staffing requirements as CA pharmacies?**

Answer: No.

A non-resident pharmacy (NRP) is a pharmacy located in another state that furnishes dangerous drugs to patients in CA, and is required to be licensed with the board. Part of the licensure requirement is that the NRP be in compliance with pharmacy laws in the state where it is located.

The board has no authority to dictate staffing requirements for pharmacies located in states other than CA. The board expects the NRP to be staffed in accordance with requirements where it is located.

Reference: Business and Professions Code § 4112(a); 4112(d)

4. Question: **What constitutes sterile compounding?**

Answer: First, let's define "compounding" in general:

"Compounding" means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:

(1) Altering the dosage form or delivery system of a drug
(2) Altering the strength of a drug
(3) Combining components or active ingredients
(4) Preparing a drug product from chemicals or bulk drug substances

With the above in mind, sterile compounding is a specific sub-type of general compounding whereby there is a requirement for the compounded drug product to be sterile. Sterile compounding almost exclusively involves sterile parenteral compounding for which there are additional requirements.

Reference: CCR §§ 1735(a) 1735(d); 1751 et seq.

5. Question: **Is the adding of 20 mEq of potassium chloride to 1000cc of normal saline for intravenous administration considered sterile compounding.**

Answer: Yes, and this is also considered sterile parenteral compounding

Reference: CCR 1735(a)

6. Question: **Can a pharmacy mix three liquids (Maalox, Benadryl, and Xylocaine) in equal parts or two creams in equal parts, and would this be considered compounding.**

Answer: Yes in the examples given, a pharmacy may mix those products in equal parts. And yes, it is considered compounding.

Reference: CCR 1735(a)

7. Question: **What happens in a situation where an IV is made to be used on a one- time basis for administration within 24 hours for a registered in-patient of a health care facility and the IV product is not used and returned to the pharmacy? Can it be reused?**

Answer: No.

The compounding regulations require specific records for compounded drug products. For each compounded drug product, the pharmacy records shall include:

(1) The master formula record.
(2) The date the drug product was compounded.
(3) The identity of the pharmacy personnel who compounded the drug product.
(4) The identity of the pharmacist reviewing the final drug product.
(5) The quantity of each component used in compounding the drug product.
(6) The manufacturer and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. Exempt from the requirements of this paragraph are sterile products compounded on a one-time basis for administration within twenty-four hours to an in-patient in a health care facility.
(7) The equipment used in compounding the drug product.
(8) A pharmacy assigned reference or lot number for the compounded drug product.
(9) The expiration date of the final compounded drug product.
(10) The quantity or amount of drug product compounded.

If all the information is not recorded [as provided by the exemption in (6)] then there is a lack of complete traceability and accountability for the compounded drug product and thus it cannot be reused.

Reference: CCR 1735.3(a)

8. Question: **Our medical center's policies and procedures have the initial dose of an IV admixture compounded in the pharmacy satellite to assure timely initiation of therapy, with all subsequent doses mixed in the central pharmacy.**

Is the initial IV admixture compounded in the satellite pharmacy subject to the record keeping requirements?

Answer: Yes, with the possible exception of documenting the manufacturer and lot number of each component of the admixture.

Reference: CCR 1735.3(a)(6)

9. Question: **Is a master formula record equivalent to a "recipe card?"**

Answer: Basically, yes.

Like a recipe card the master formula record includes the active and inactive ingredients to be used, the process and/or procedure used to prepare the drug, quality reviews required at each step in the preparation of the drug, post-compounding process or procedures required, and the expiration dating requirements.

The master formula record must be created prior to compounding the drug product.

The prescription document itself may be used as the master formula record If a pharmacy does not routinely compound a particular drug product.

Reference: CCR 1735.2(d)

10. Question: **When compounding a product, is it required to have master formula record available and used when the product is compounded?**

Answer: Yes, the master formula record must be created prior to compounding the drug product and its use will provide guidance for compounding personnel and consistency in the product produced.

Reference: CCR 1735.2(d)

11. Question: **Is it required to review the master formula record as part of pre-check process?**

Answer: The law is silent on a "pre-check process." However, the master formula record will provide guidance to compounding personnel in what to use and how to compound the particular drug product. So the master formula record could be used in a "pre-check" process to insure consistency in the compounding process.

Reference: CCR 1735.3

12. Question: **What are the requirements for compounding documentation?**

Answer: The compounding regulations require specific records for compounded drug products. For each compounded drug product, the pharmacy records shall include:

(1) The master formula record.
(2) The date the drug product was compounded.
(3) The identity of the pharmacy personnel who compounded the drug product.
(4) The identity of the pharmacist reviewing the final drug product.
(5) The quantity of each component used in compounding the drug product.
(6) The manufacturer and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. Exempt from the requirements of this paragraph are sterile products compounded on a one-time basis for administration within twenty-four hours to an in-patient in a health care facility.
(7) The equipment used in compounding the drug product.
(8) A pharmacy assigned reference or lot number for the compounded drug product.
(9) The expiration date of the final compounded drug product.
(10) The quantity or amount of drug product compounded.

Reference: CCR 1735.3

13. Question: **When using the record-keeping exemption in 1735.3(a)(6) to compound a one-time Vancomycin IV with a seven-day expiration date and to be used within 24 hours, is the manufacturer and lot number required?**

Answer: No.

The regulations provide for an exemption for sterile products compounded on a one-time basis for administration within twenty-four hours to an in-patient of a health care facility.

Reference: CCR 1735.3(a)(6)

14. Question: **When must the manufacturer and lot number be recorded?**

Answer: This information must be documented if the product is not for a one-time use for a specific patient to be used within 24 hours.

Reference: CCR 1735.3(a)(6)

15. Question: **How will the board insure compliance by non-resident pharmacies (NRP's) that provide compounded drug products into CA?**

Answer: The board does not have the ability to inspect NRPs.

However, NRPs are required to be licensed with the board and to maintain compliance with pharmacy regulations of their home state. Also, a NRP performing sterile parenteral compounding as a condition of renewal will be encouraged to submit a completed Compounding Self Assessment Form.

Reference: B&P §§ 4112, 4127.2

16. Question: **Is the dilution per the manufacturer's instructions and adding to the IV solution considered compounding?**

Answer: Yes, if done in a pharmacy. However, statute provides for exemption from sterile compounding licensure if the sterile powder was obtained from a manufacturer and the drug is reconstituted for administration to patients by a health care professional licensed to administer drugs by injection.

Reference: CCR 1735(a)(1); B&P 4127.1(e)

17. Question: **Are proprietary drug delivery systems such as ADD-Vantage, Mini-Bag Plus, and At-Eas considered compounded products after the vials have been attached to the IV bags?**

Answer: These types of delivery systems are exempt from the compounding requirements if the sterile powder was obtained from a manufacturer and the drug is reconstituted for administration to patients by a health care professional licensed to administer drugs by injection.

Reference: CCR 1735(a)(1); B&P 4127.1(e)

18. Question: **What specifically will be required or what process is acceptable to achieve quality assurance?**

Answer: Quality assurance, as the term implies, is designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded products.

A quality assurance plan will touch all parts of the compounding process – drug product and equipment acquisition/storage; compounding processes; documentation of compounding and related analysis; employee training and monitoring; recall procedure; etc

Reference: CCR §§ 1735.8; 1735.3; 1735.5; 1735.6; 1735.7; 1751 et seq

19. Question: **When recycling an IV that was previously compounded by the pharmacy, can the previous lot number of the recycled IV be used as long as the lot number can be traced to all the requirements listed in section 1735.3(a)?**

Answer: Yes.

Reference: CCR 1735.3(a)

20. Question: **Does every product and/or formulation compounded by a pharmacy have to undergo qualitative and quantitative analysis? If not, can the board provide guidance for selecting products to be analyzed?**

Answer: The pharmacy, and the pharmacist, are responsible for insuring the compounded product complies quantitatively and qualitatively with the prescriber's prescription.

For compounded product that is compounded on a one-time basis for immediate dispensing, it would not be likely there would be a quantitative or qualitative analysis conducted.

For products compounded for on-going therapy it would be expected there would be analysis done initially and on a periodic basis to validate the product and compounding process.

The same holds true for sterile injectable drug products too.

However, if two or more sterile injectable drug products being compounded from one or more non-sterile ingredients, these end-products shall be quarantined until end-product testing confirms sterility and acceptable levels of pyrogens.

Reference: CCR §§ 1735.2(f); 1735.2(i); 1751.7(a); 1716

21. Question: **Does CCR section 1735.5 require a pharmacy to test each and every compounded product for integrity, potency, quality, and labeled strength of the compounded product?**

Answer: No. However, if the compounded product involves a complex process it would seem prudent to have documentation of the final product. This is even more important when the product is compounded on a more routine basis.

Compounding involves not just the QA process, but staff training, equipment maintenance, proper documentation and appropriate analysis of products compounded.

Reference: CCR 1735.8; 1735.3; 1735.5; 1735.6; 1735.7; 1751 et seq.

22. Question: **For the purposes of CCR section 1735.3(a)(6) and 1751.2(a), would patients receiving chemotherapy administered in an infusion center that is part of a health care facility be considered "in-patients" and exempt from the labeling requirements?**

Answer: If the infusion center is part of the licensed health care facility and the patients receiving care there are registered as hospital in-patients, then yes the exemption provided by CCR 1735(a)(6) would apply. However, the labeling requirements as defined in CCR 1751.2 would apply and compliance would be expected.

Reference: B&P §§ 4027, 4019, 4029; CCR 1735.3(a)(6), 1751.2

23. Question: **CCR section 1735.3 defines what must be recorded for each compounded drug product. CCR 1735.3(a)(7) states, "The equipment used in compounding the drug product." Does this include tubing sets, spikes, needles, syringes, etc.?**

Answer: Yes, all equipment used for compounding the drug product must be recorded – TPN compounders, homogenizers, scales, syringes, needles, tubing sets, spikes, filters, mortar and pestle, pill making device, infusion devices. If there are more than one of the same device (e.g. - scales, laminar flow hoods) it is recommended to label them in some manner to distinguish which one was used in the process for appropriate completion of the compounding record.

Reference: CCR 1735.3(a)(7)

24. Question: **Where would the lot number, manufacturer, and expiration date be recorded?**

Answer: The law does not specify where or how the information is to be recorded. A pharmacy may develop it own form(s) for the proper documentation. The pharmacy shall maintain the record for three years from the date it was created.

Reference: CCR 1735.3

25. Question: **CCR section 1751.2(d) states, "All cytotoxic agents shall bear a special label which states 'Chemotherapy – Dispose of Properly.'" This appears to give no wiggle room for the text of the message.**

Answer: There are no exceptions. If a drug is classified as a cytotoxic agent then the special label must be used.

Reference: CCR 1751.2(d)

26. Question: **Gancyclovir is a cytotoxic agent but is not a chemotherapeutic agent. Does the special label need to be applied?**

Answer: Yes, the regulation does not provide for exceptions. However, nothing prevents the pharmacist from consulting the patient on the drugs classification and use.

Reference: CCR 1751.2(d)

27. Question: **CCR section 1751.5(b)(1) states, in pertinent part, "Cleanroom garb consisting of low-shedding coverall, head cover…must be worn inside the designated area at all times." USP 797 does not require the use of a coverall, only a gown.**

Answer: The board does not enforce USP 797, but expects compliance with board regulations.

A coverall is much more encompassing than a gown and would provide better protection during the compounding process.

Reference: CCR 1751.5(b)(1)

28. Question: **For a compounded drug product can a pharmacy use an expiration date, or beyond use date, of greater than 180 days?**

Answer: Yes, if the longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging.

Reference: CCR 1735.2(h)

29. Question: **If a pharmacy makes a compounded drug product and does the qualitative and quantitative testing that demonstrates it has a stability expiration dating greater than 180 days, can another pharmacy use the same formula, with minor changes, use the same extended expiration date?**

Answer: No. To use another pharmacy's extended expiration date the formula must use the same components and packaging.

Reference: CCR 1735.2(h)

30. Question: **Master formulas and compounding records are filed in separate locations, can easily be linked together, and are readily retrievable. Is it an absolute requirement to file these documents together?**

Answer: No, there is no such requirement for the above records to be maintained together as long as they are readily retrievable and available for inspection. These records may be maintained in a paper or electronic manner.

However, qualitative and quantitative analysis reports for compounded drug products shall be retained by the pharmacy and collated (kept together) with the compounding record and master formula.

Any records that are maintained electronically shall be maintained so that the pharmacist-in-charge or the pharmacist on duty shall during business hours be able to produce a hard copy and electronic copy.

Reference: CCR 1735.8(c); B&P 4105(d)

31. Question: **Is record keeping for compounding just referring to products that are administered intravenously or intraocular (e.g. where sterile preparation is imperative) or does it extend to oral and topical compounding?**

Answer: The regulations apply to all forms of compounding – oral, inhalation, topical, sterile parenteral, etc. The record keeping requirements for sterile compounding are more extensive

Reference CCR §§ 1735 et seq & 1751 et seq.

32. Question: **What is meant by proper acquisition?**

Answer: Records of proper acquisition of dangerous drugs and dangerous devices would include purchase records that correctly give the date, the names and address of the supplier and the buyer, the drug or device, and its quantity.

Also, refer to Question #1 and its answer.

Reference: B&P § 4059(b)

Attachment 6

November / December 2009

MedWise: Preventing Medication Waste While Promoting Safe Administration

By Jeffrey Conzelmann, PharmD; Karyl King, PMP; Sharon Sarnicola, RN; and Brenda Wierenga, RN, BSN

Hospitals face a frustrating medication dilemma: should inpatients be allowed to take their multi-dose medications (e.g., inhalers, topical creams, eye drops, insulin) home upon discharge? The natural inclination is for patients to ask, "These are paid for; why can't I take them home? What's the big problem?"

The problem is to comply with federal regulations for the labeling of medications that are sent home. Regulations require that any medication a patient takes home must be labeled as if it were coming from an outpatient pharmacy. If these labeling requirements cannot be met, then the multi-dose medications must be discarded (Michigan Public Health Code, 2008). This labeling requirement creates difficulties, but on the other hand, it seems that no one is served when expensive medications are thrown away.

At Spectrum Health in Grand Rapids, Michigan, three of us — two RNs and a pharmacist — addressed that dilemma as a work team. Instead of just accepting the status quo, we went to Spectrum Health's Innovation Lab — What I.F.? — and enlisted the help of its project manager. Together, we presented our concern to a leadership team, the Spectrum Health Innovation Committee, which includes executive-level administrators from finance, information and technology services, marketing and communications, medical affairs, research and education, patient affairs, general counsel office, and is chaired by the president.

Some of the questions discussed initially included:

- How can Spectrum Health document and track medication history at discharge while complying with all federal and state regulations?
- How can we create a virtual outpatient pharmacy function at the point of discharge that converts inpatient multi-dose medications to outpatient medications for home use?
- What labeling is required and appropriate?
- What patient education services are needed?

The Innovation Committee gave its approval for the work team to begin an initiative called "MedWise" to conduct a literature search, collect data, and obtain an independent legal opinion.

Literature Search and Data Collection

First, we conducted a literature search to determine if any other hospitals had implemented similar programs. That search resulted in finding little or no information. Second, we carried out an internal data analysis to try to validate our assumption. Were we, in fact, wasting valuable resources?
The data showed that the average potential out-of-pocket cost for multi-dose medications per patient was $120; the range was between $6 and $520. In another component of our data analysis, a sampling was kept of medications thrown away from all types of inpatients at Spectrum Health's Blodgett Hospital for the week of July 2, 2007. *The total value of those medications was approximately $5,000.* We also kept a sampling of medications thrown away from all types of inpatients at the other major Spectrum Health hospital — Butterworth Hospital — for the week of August 6, 2007. *The total value of those medications was approximately $25,000.* Annualized, the total value of medications thrown away at both facilities was a staggering $1,560,000!

Legal Analysis

Based on recommendations from the Spectrum Health Risk and Compliance Department, we requested an independent legal opinion.
In its opinion, the firm stated that neither the Michigan Public Health Code (2008) nor the Board of Pharmacy's General Rules (R 338.471) directly address the question of whether patients may take home unused portions of medications dispensed to them while they are in the hospital. However, the destruction of unused medication dispensed to hospital patients is not an absolute requirement; single-use packages and IV solutions designed to be tamper-evident and which show no evidence of tampering may be returned to stock. On the other hand, medications that leave the institution may not be returned to stock for redispensing. Thus, the General Rules implied that medications can leave the hospital with the patient at discharge.

Technology Solution

Based on all of these preliminary findings, the work team returned to the Spectrum Health Innovation Committee and was given permission to find a solution. After rechecking the literature for potential appropriate solutions and not finding any, we began to evaluate the various types of technology options within our system.
The first option we investigated was to create one label that provided all the required information, but existing systems were not able to accurately differentiate between multi-dose and other types of medications. The second option we evaluated was the use of a generic preprinted label added to the Cerner patient barcode label (Figure 1). This solution proved to be workable within our system, and it met all federal and state regulations regarding properly labeling medication for dispensing at discharge.

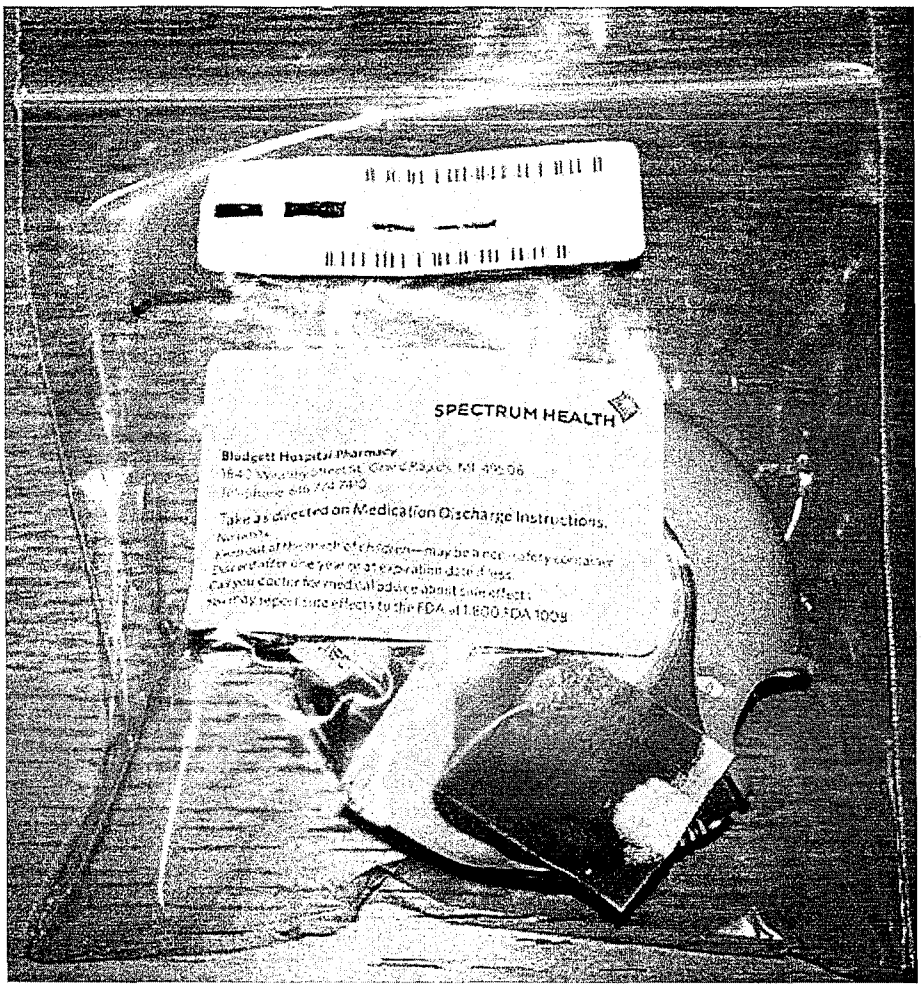

Figure 1: Labeling Solution: Generic Hospital Label with Cerner Patient Barcode

Policy Requirements

While we were designing the technology solution, we also began to revise our policy related to dispensing medications to discharged and clinic patients. The revised policy, which needed to address both the processes for dispensing and patient education issues, states that:
Multi-dose medications including inhalers, ophthalmic products, insulin products, and topical preparations may be provided to patients upon discharge provided the following criteria have been met (injectable medications other than insulin products are excluded):

- The specified multi-dose product must be a continuation of hospital-initiated therapy.
- The physician must write a physician order in the chart indicating that the multi-dose product may be sent home with the patient.
- The product must be labeled according to federal labeling requirements:
    - Pharmacy will label the product prior to dispensing for inpatient use with the following information: the patient name, product name and strength, and date of initial dispensing.
    - Pharmacy will then dispense initial product in a clear plastic bag with a label on the plastic bag indicating name, address, and phone number of the hospital pharmacy. The label will contain instructions for use by the patient as indicated on the patient's discharge medication sheet. The label will include the statement: "Discard this medication one (1) year after the date it is dispensed or on the manufacturer's expiration date, whichever is sooner."
    - Once initial product is received by the nursing unit, a patient label will be placed on the bag by the nurse. This label will include the patient name, numerical identifier, and attending physician.
    - The multi-dose product will be maintained in the plastic bag during the patient's hospital stay and be kept in the patient's locked medication drawer.
    - The patient must be provided the opportunity for counseling from nursing, pharmacy, or a licensed independent practitioner; questions regarding their medications must be addressed and documented. Documentation of this activity is entered on the patient's education record.
    - If a licensed independent practitioner does not want the patient to take home the hospital-issued multi-dose medication, but does desire the patient to continue therapy, the practitioner must provide the patient with a written prescription. A record of such discharged prescriptions must be noted in the patient's chart.

The Emergency Department (ED) follows the same process, except patients discharged from the ED may receive starter medications when circumstances prevent prompt access to prescriptions through an outpatient pharmacy.

Education and Communication Strategy

Once a technology solution was defined, the entire process was reviewed with the key stakeholders: the Nursing Education Committee, hospitalists, nursing leadership, the pharmacy, and the risk and compliance leadership.
After obtaining approval from all key stakeholders, we worked with nursing education to define the educational requirements. These included developing an online training course, information about the new policy, information about the change in process, a Frequently Asked Questions flier, and a description of new roles and tasks for nursing staff.

A critical key to successful change was to ensure we had a broad, far-reaching communication plan that targeted the entire hospital as well as external independent practitioners. We leveraged a variety of vehicles to communicate the change in medication dispensing, its rationale, the change in process, and new role definitions. These included the use of Hot Topics (a monthly physician newsletter), department meetings, a letter to physicians from senior management, and various announcements and memos to everyone involved.

We decided to launch the MedWise initiative in two phases approximately 6 weeks apart. Phase 1 focused on Blodgett Hospital, which has 297 beds. Phase 2 targeted Butterworth Hospital, which has 614 beds, and Helen DeVos Children's Hospital, which has 152 beds.

An important part of the launch involved communicating the benefits of the change to patients, their families, physicians and other practitioners, payers, and the community. These included:

- Improve patient satisfaction by enhancing their quality of life and reinforce our partnership by providing them with an exceptional experience.
- Improve fiscal responsibility for expensive resources.
- Safe and responsible use of resources in a manner that supports our hospital polices, federal and state regulations.

Measuring Success and Course Correction

To define success for the MedWise initiative and determine any ongoing changes needed, we identified two measurement procedures:

- Include in our quality audits an evaluation of the medication reconciliation discharge form to ensure that every form contains three signatures (physician, patient, and nurse).
- Collect medication returns to the pharmacy at each hospital location to determine if there has been a reduction in returns.

Currently, we are in the implementation phase of the initiative. Although we are early in the implementation phase, we are seeing a reduction in medication waste by 50%, and staff and patients report positive feedback as they follow the new process. We are partnering with the Spectrum Health Quality Department to evaluate the audit results, offer further education, and review the new policy as appropriate.

Spectrum Health

Spectrum Health is a not-for-profit health system in West Michigan that offers a full continuum of care through the Spectrum Health Hospital Group, a collection of seven hospitals and more than 140 service sites; the Spectrum Health Medical Group, a multispecialty team of nearly 100 providers; and Priority Health, a health plan with nearly 500,000 members. Spectrum Health's 14,000 employees, 1,500 medical staff members, and 2,000 volunteers are committed to delivering the highest quality care to those in medical need. The organization provided $111.1 million in community benefit during its 2008 fiscal year. As a system, Spectrum Health has earned more than 100 awards during the past 10 years.

Value of MedWise

Before implementing MedWise, there were times when patients with limited resources had to choose between paying for medication they received in the hospital or taking care of their other needs. By implementing the MedWise process we are:

- Allowing them to take home their unused multi-dose medications. This increases patient satisfaction and is seen as actively "doing the right thing" for our consumers and their families.
- Engaging physicians and staff more fully in promoting patient safety and compliance in medication dispensing.
- Being fiscally and environmentally responsible by decreasing medication waste.

An additional benefit for the hospital involves our patient leave-of-absence policy. The MedWise initiative allows the hospital to remain in compliance with federal and state regulations while patients take needed medications with them during a leave defined in their clinical path.

Conclusion

The MedWise initiative is new and initial evaluation is incomplete. As technology changes with the introduction of computerized provider order entry (CPOE), we know we will need to revise our process to ensure an easy transition from paper orders to computerized orders.
However, it appears we have successfully created a virtual pharmacy that allows patients to take home their prescribed and paid-for medications. Initial feedback from Spectrum Health staff supports the MedWise initiative. It is seen as actively "doing the right thing" for patients while being fiscally and environmentally responsible by decreasing medication waste.

Jeffrey Conzelmann has been a practicing pharmacist for 20 years, both as a staff pharmacist and for 5 years as a clinical pharmacist specializing in cardiology. He has served on various continuous improvement teams focused on heart failure and acute myocardial infarction, with responsibility for ensuring that patients receive appropriate therapies indicated by national guidelines. He is currently the pharmacy manager for Blodgett Hospital at Spectrum Health in Grand Rapids. Conzelmann earned his bachelor of science in pharmacy from Ferris State University and his PharmD from the University of Florida.

Karyl King has 18 years of leadership in project management, specifically in developing project management methodologies in the new product development and healthcare industries. She has extensive experience in leading and working collaboratively with team members to complete projects in new product development, quality enhancement, rapid tooling, and information technology development, using the Toyota lean methodology for process improvement. She is currently a project manager at Spectrum Health, leading innovation projects through

the What I.F.? Innovation Lab. King graduated from Davenport University with a bachelor's degree in general business and currently serves on the board for the West Michigan Project Management Chapter. She may be contacted at Karyl.King@spectrum-health.org .

Sharon Sarnicola has been in nursing for 25 years, the last 23 of which have been with Spectrum Health in Grand Rapids. Her nursing background includes positions as a critical care nurse in neurology and medical critical care, endoscopy, and as a clinical manager. Sarnicola is currently a coordinator in the patient relations department. She graduated with an associate of science nursing degree from Lansing Community College.

Brenda Wierenga has been in nursing for 21 years with Spectrum Health in Grand Rapids. She has served as a neuroscience bedside nurse, a neuro-trauma and rehabilitation nurse manager, and neuro care manager. She is currently a coordinator in the patient relations department. She earned her bachelor of science in nursing degree from Hope College.

References

Michigan Public Health Code. (2008). Article 15, Michigan Board of Pharmacy's General Rules (R 338.471).

Last Updated on Friday, 13 November 2009 11:14

Attachment 7

DCA’s Enforcement Performance Measures will be provided at the meeting. The link provided on the Web site was inoperative.

Board of Pharmacy Enforcement Statistics
Fiscal Year 2010/2011

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 10/11
Complaints/Investigations					
Received	565	592			1157
Closed	754	632			1386
Pending (at the end of quarter)	1151	1229			1229
Cases Assigned & Pending (by Team)					
Compliance Team	394	324			324
Drug Diversion/Fraud	98	121			121
Probation/PRP	85	82			83
Mediation/Enforcement	74	14			14
Criminal Conviction	475	518			518
Application Investigations					
Received	181	217			398
Closed					
Approved	85	147			232
Denied	23	31			54
Total*	150	251			401
Pending (at the end of quarter)	448	432			432
Letter of Admonishment (LOA) / Citation & Fine					
LOAs Issued	65	36			101
Citations Issued	307	293			600
Citations Closed	339	358			697
Total Fines Collected**	$191,990.00	$316,395.00			$508,385.00

* This figure includes withdrawn applications.

** Fines collected (through 12/31/2010) and reports in previous fiscal year.

Board of Pharmacy Enforcement Statistics
Fiscal Year 2010/2011

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 10/11
Administrative Cases (by effective date of decision)					
Referred to AG's Office*	104	97			201
Pleadings Filed	82	65			147
Pending					
Pre-accusation	179	197			197
Post Accusation	254	271			271
Total*	508	496			496
Closed**					
Revocation					
Pharmacist	2	1			3
Pharmacy	0	0			0
Other	17	28			45
Revocation,stayed; suspension/probation					
Pharmacist	5	2			7
Pharmacy	0	0			0
Other	0	0			0
Revocation,stayed; probation					
Pharmacist	2	3			5
Pharmacy	1	2			3
Other	1	3			4
Suspension, stayed; probation					
Pharmacist	0	0			0
Pharmacy	0	0			0
Other	0	0			0
Surrender/Voluntary Surrender					
Pharmacist	2	1			3
Pharmacy	1	1			2
Other	12	8			20
Public Reproval/Reprimand					
Pharmacist	0	0			0
Pharmacy	0	0			0
Other	0	0			0
Cost Recovery Requested	$108,566.50	$117,558.50			$226,125.00
Cost Recovery Collected	$38,755.24	$74,313.04			$113,068.28

* This figure includes Citation Appeals

** This figure includes cases withdrawn

Board of Pharmacy Enforcement Statistics
Fiscal Year 2010/2011

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 10/11
Probation Statistics					
Licenses on Probation					
Pharmacist	99	103			103
Pharmacy	8	11			11
Other	27	30			30
Probation Office Conferences	51	26			77
Probation Site Inspections	36	53			89
Probationers Referred to AG for non-compliance	1	0			1

As part of probation monitoring, the board requires licensees to appear before the supervising inspector at probation office conferences. These conferences are used as 1) an orientation to probation and the specific requirements of probation at the onset, 2) to address areas of non-compliance when other efforts such as letters have failed, and 3) when a licensee is scheduled to end probation.

Pharmacists Recovery Program (as of 12/31/2010)

Program Statistics					
In lieu of discipline	1	0			1
In addition to probation	3	3			6
Closed, successful	0	6			6
Closed, non-compliant	1	0			1
Closed, other	2	1			3
Total Board mandated Participants	45	55			55
Total Self-Referred Participants*	30	22			22
Treatment Contracts Reviewed	73	61			134

Monthly the board meets with the clinical case manager to review treatment contracts for scheduled board mandated participants. During these monthly meetings, treatment contracts and participant compliance is reviewed by the PRP case manager, diversion program manager and supervising inspector and appropriate changes are made at that time and approved by the executive officer. Additionally, non-compliance is also addressed on a needed basis e.g., all positive urines screens are reported to the board immediately and appropriate action is taken.

* By law, no other data is reported to the board other than the fact that the pharmacists and interns are enrolled in the program.

As of December 31, 2010

Attachment 8

California State Board of Pharmacy
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www.pharmacy.ca.gov

STATE AND CONSUMERS SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
ENFORCEMENT COMMITTEE
MINUTES

DATE: December 6, 2010

LOCATION: Department of Consumer Affairs
First Floor Hearing Room
1625 N. Market Boulevard
Sacramento, CA 95834

COMMITTEE MEMBERS PRESENT: Randy Kajioka, PharmD, Chair
Greg Lippe, Public Member, Treasurer
Ramón Castellblanch, Public Member

COMMITTEE MEMBERS NOT PRESENT: Tappan Zee, Public Member

STAFF PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Joshua Room, Deputy Attorney General (Via Conference Phone)
Kristy Shellans, DCA Staff Counsel
Carolyn Klein, Legislation and Regulation Manager
Susan Cappello, Enforcement Manager
Tessa Miller, Staff Analyst

Call to Order

Chair Kajioka called the meeting to order at 1:35 p.m.

Chair Kajioka conducted a roll call. Committee members Kajioka, Lippe, and Castellblanch were present.

1. Presentations to Request Exemptions from 16 California Code of Regulations Section 1707.5 Label Requirements for Prescription Drug Containers as Authorized by Section 4076.5 (SB 1489, Negrete-McLeod, Chapter 653, Statutes of 2010)

Chair Report

Chair Kajioka provided background on this issue. He stated that effective January 1, 2011, the board's requirements for patient-centered labels go into effect as 16 California Code of Regulations Section 1707.5.

Chair Kajioka indicated that also effective January 1, 2011, provisions enacted by SB 1489 (Senate Business and Professions Committee, Chapter 653, Statutes of 2010) as amendments to Business and Professions Code section 4076.5, allow the board to exempt from the labeling requirements prescriptions dispensed to patients in certain environments.

Chair Kajioka advised that to allow such an exemption, the board will need to promulgate regulations.

Request from Medco for Infusion Pharmacies

Dennis McAllister and Don Filibeck, representing Medco, requested an exemption from the patient-centered labeling requirements of section 1707.5 for 6 California infusion pharmacies that are part of the Accredo Health Group, Inc. and affiliates. Mr. McAllister and Dr. Filibeck provided an overview of how infusion pharmacies operate and explained how they can provide appropriate consumer protection and education without the patient-centered labels.

Mr. McAllister discussed that home infusion and specialty pharmacy practices are "high touch" in nature and exceed patient education and safety that is intended by the requirements.

Dr. Filibeck provided that the pharmacies satisfy the following requirements of SB 1489. The specific exemption for infusion pharmacies occurs in Business and Professions Code section 4076.5(e) (effective 1/1/11):

> (e) (1) The board may exempt from the requirements of regulations promulgated pursuant to subdivision (a) a prescription dispensed to a patient if all of the following apply:
> (A) The drugs are dispensed by a JCAHO-accredited home infusion or specialty pharmacy.
> (B) The patient receives health-professional-directed education prior to the beginning of therapy by a nurse or pharmacist.
> (C) The patient receives weekly or more frequent followup contacts by a nurse or pharmacist.
> (D) Care is provided under a formal plan of care based upon a physician and surgeon's orders.

(2) For purposes of paragraph (1), home infusion and specialty therapies include parenteral therapy or other forms of administration that require regular laboratory and patient monitoring.

Dr. Filibeck indicated that the pharmacies are fully accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).

Dr. Filibeck discussed that patients are provided health-professional-directed education and open communication between patients and staff to ensure appropriate and comprehensive care is provided. He stated that a plan of care is developed in conjunction with the patient's physician.

Mr. McAllister and Dr. Filibeck reviewed sample labels provided to the committee and expressed concern that a larger or longer label, resulting from increased labeling requirements, may not be able to be appropriately attached to the medication.

Mr. McAllister provided that this exemption is needed to provide safe and effective care to patients.

Discussion

Mr. Lippe asked whether the exemption is being requested because of cost.

Dr. Filibeck provided that the request is being made in the interest of patient safety. He discussed that the objective is to assist patients with being self sufficient and independent in their care.

Mr. McAllister provided that the size of the label is a significant issue. He discussed the use of mini-bags and advised that large labels cover the majority of the bag and restrict the patient's ability to see any particulate matter.

Dr. Castellblanch sought clarification regarding the frequency of a patient's regular contact with a nurse or pharmacist.

Dr. Filibeck provided that the frequency of contact is dependent on the therapy. He indicated that most home infusion requires weekly contact.

Dr. Castellblanch reviewed the instructions provided on the sample labels. He expressed concern regarding technical terms used on the examples. Dr. Castellblanch discussed the importance of patient and caregiver comprehension and competence.

Dr. Filibeck provided that appropriate support is provided and in some cases daily visits by a nurse are provided until all family members or caregivers feel comfortable with administration of the medication.

Mr. McAllister discussed the special nature of this type of care and stated that it is different than chronic care.

Chair Kajioka commended Medco for its multidisciplinary efforts to educate patients. He expressed concern regarding readability of the label. Chair Kajioka asked whether Medco could comply with the font size requirement.

Dr. Filibeck discussed the possibility of offering additional materials to help support the label. He stated that patients are initially assessed to determine that they are viable candidates for treatment at home.

Chair Kajioka asked how the quality of care is mandated.

Dr. Filibeck stated that JACHO requires a care planning process requirement.

Mr. McAllister discussed that this type of care is specific and does not involve the general population.

Mr. Lippe discussed that the request appears to meet the requirements for the exemption.

Executive Officer Virginia Herold announced that Deputy Attorney General Joshua Room is available for comment via conference phone.

Ms. Herold asked whether a patient's comprehensive drug therapy is being monitored by the pharmacy.

Mr. McAllister provided that other medications will be noted in the patient's log. He confirmed that the Medco Pharmacies are only providing the patient with the specialty medications as required by their infusion therapy.

Ms. Herold expressed concern regarding the technical information included on the sample labels.

Mr. McAllister and Dr. Filibeck provided assurance that appropriate support and supplemental information will be provided to the patient.

Ms. Herold advised that the statute requires weekly or more frequent follow up by a nurse or pharmacist. She stated that patients on 30 day monitoring would not qualify for this exemption.

Dr. Filibeck indicated that Medco will comply with this requirement.

Dr. Castellblanch sought clarification regarding dose changes and how this would be indicated on the label.

Dr. Filibeck provided that dose changes occur with the next delivery of the medication. He stated that patients will be notified regarding dose changes.

Chair Kajioka discussed that medication information is discussed during consultation between the pharmacist and the patient as well as between the physician and the patient. He provided that label information is supplemental to the information provided during consultation.

Dr. Filibeck provided that patients are consulted before a change is made to their medication.

Mr. Lippe asked whether patients are asked whether or not they understand the changes being made.

Dr. Filibeck discussed that patients are counseled to ensure they understand and are comfortable with their medication.

Dr. Castellblanch asked what font size is used on the example labels.

Dr. Filibeck provided that he is unsure of the exact font size used on the label.

Ms. Herold stated that a significant segment of the population in California can not read English. She asked if the labels can be printed in other languages.

Dr. Filibeck indicated that the labels can be translated into Spanish. He stated that there are available resources to print labels and supplemental materials in other languages.

Supervising Inspector Robert Ratcliff discussed the example labels provided by Medco. He stated that the labels appear to have more than 50 percent of white space and asked why this space can not be used to satisfy the patient-centered labeling requirements.

Dr. Filibeck provided that the white space is used to increase readability for patients to easily locate label information. He stated that patients are educated to look in specific areas to locate certain pieces of information.

Dr. Ratcliff asked whether Medco will comply with the requirement to list specific elements in a specified order as required by the regulation.

Dr. Filibeck provided that the order of label information can be changed.

Dr. Ratcliff discussed the ability for other organizations to rework their current labels in order to comply with the new requirements of the regulation.

Public Comment

Fred Mayer, representing the California Alliance for Retired Americans (CARA), urged the board to not grant this exemption. He provided comment on the importance of maintaining readability and reducing medication errors. Mr. Mayer suggested that the

board not act on this request until Medco can specify a specific font size that will be used on their labels.

Al Carter, representing Walgreens, provided support for the request. He discussed that it is difficult to create a standardized label to meet the needs of this specialized and specific group.

Mr. Lippe asked what size font is currently being used by Walgreens infusion pharmacies.

Mr. Carter provided the committee with a copy of a standard label in a 10-point font currently being used.

The committee reviewed the label. Ms. Herold requested that Medco provide additional sample labels before the February 2011 Board Meeting.

Mr. Carter provided that Walgreen's chain pharmacies and infusion pharmacies will comply with the labeling requirements. He stated that the labels meeting these requirements should be implemented by late January 2011.

There was no additional discussion or public comment.

Request from CPhA's Long-Term Care Academy

Paige Tally, representing the California Pharmacists Association (CPhA), asked the committee to recommend to the full board an exemption from SB 1489 in 4076.5(d) for skilled nursing facilities as allowed by the following:

> (d) The board may exempt from the requirements of regulations promulgated pursuant to subdivision (a) prescriptions dispensed to a patient in a health facility, as defined in Section 1250 of the Health and Safety Code, if the prescriptions are administered by a licensed health care professional. Prescriptions dispensed to a patient in a health facility that will not be administered by a licensed health care professional or that are provided to the patient upon discharge from the facility shall be subject to the requirements of this section and the regulations promulgated pursuant to subdivision (a). Nothing in this subdivision shall alter or diminish existing statutory and regulatory informed consent, patients' rights, or pharmaceutical labeling and storage requirements, including, but not limited to, the requirements of Section 1418.9 of the Health and Safety Code or Section 72357, 72527, or 72528 of Title 22 of the California Code of Regulations.

Ms. Tally provided an overview of skilled nursing facilities and stated that these facilities contract with a long-term care facility to provide medications. She stated that medication is securely maintained and is administered to the patients by either a

licensed nurse or a trained medication administrator. Ms. Tally indicated that patients do not need to understand the label directions on their medication containers as they do not receive these containers.

Ms. Tally stated that the new labeling requirements are intended for the regular outpatient population and would not significantly improve care in skilled nursing facilities.

Discussion

Mr. Lippe provided that he reviews all of his medication prior to administration during stays in the hospital.

Ms.Tally provided that this exemption is being requested for skilled nursing facilities and not for hospital settings. She discussed that it is not typical for a skilled nursing facility patient to request to review their medication.

Mr. Lippe asked Ms. Tally if she is aware of the percentage of medication errors that occur in skilled nursing facilities.

Ms. Tally provided that she is unaware of this number. She offered to provide this information for the February 2011 Board Meeting.

Dr. Castellblanch asked how a patient in a skilled nursing pharmacy would be able to evaluate their medication if desired. He sought clarification regarding whether this medication contains a label on the container.

Ms. Tally provided that the medication is labeled.

Dr. Castellblanch requested a copy of the label being used in this setting.

Ms. Tally agreed to provide a label for the February 2011 Board Meeting.

Chair Kajioka reviewed the current labeling requirements under §4076. He indicated that these elements are required to be on the labels for medications administered in this setting.

Ms. Herold asked what will happen to the medication in the event a patient is discharged early if the exemption is granted.

Ms. Tally provided that currently this is dependent on the facility as medication can either go home with the patient or a new prescription will be issued.

Ms. Herold provided that if the exemption is granted, the medication will need to be relabeled to meet the requirements if it is sent home with the patient.

Chair Kajioka clarified that the exemption would only apply to medication labels used within the facility.

Dr. Ratcliff discussed that medication dispensed to a patient in a skilled nursing facility is the property of the patient and will need to be relabeled if it is to go home with the patient. He asked how long it would take to get medication relabeled in this setting.

Ms. Tally provided that relabeling the medication will not be a lengthy or challenging process.

Chair Kajioka provided that the committee will further evaluate this request.

Public Comment

Fred Mayer discussed that there should be standardization in this area. He expressed concern regarding the likelihood that a patient's medication will be relabeled prior to discharge.

Mr. Room clarified that this exemption would require a rulemaking to be initiated. He provided that the rulemaking process will include a hearing and the opportunity for public comment.

Ms. Herold provided comment on the complexity of this request. She stated that Ms. Tally has indicated that medication will be relabeled upon discharge of the patient to go home in order to comply with the regulation as the exemption only applies to medication within the skilled nursing facility.

Mr. Mayer cautioned the committee from granting this exemption and encouraged the board to maintain standardization.

Ms. Tally expressed concern that without the exemption, medication labels will be required to be printed in a foreign language.

DCA Staff Counsel Kristy Shellans clarified that the regulation does not require labels to be printed in a foreign language. She stated that translation services are required. Ms. Shellans indicated that the regulation does not become effective until January 2011, and as such, an exemption can not yet be granted. She advised that this discussion is only a policy discussion.

Dr. Castellblanch expressed concern regarding possible logistical problems in ensuring that medication is relabeled appropriately upon a patient's discharge.

Ms. Shellans recommended that companies interested in seeking an exemption provide data or samples to support their request. She suggested that requests contain at least the following: (1) an explanation as to why the company cannot comply with the new

requirements and (2) information regarding policies or procedures in place that address the policy concerns behind the adopted regulations.

Chair Kajioka asked Medco and CPhA to provide the requested samples for review. He requested that board staff provide direction to the companies to ensure that the requests address the committee's concerns.

2. Discussion Regarding Reporting Financial Settlements to the Board Under Sections 801-804 of the California Business and Professions Code

Chair Report

Chair Kajioka provided that the board recently undertook efforts to ensure that licensees and insurance companies are aware of their responsibilities to report to the board pursuant to sections 801 to 804 of the California Business and Professions Code. He stated that these provisions generally require the reporting to the board, by professional liability insurers and by licensees without professional liability insurance, of any settlement or arbitration award over $3,000 of any claim or action for damages or death or personal injury caused by a licensee's negligence, error, or omission in practice, or by his or her rendering of unauthorized professional services.

Chair Kajioka provided that in the September 2010 *The Script,* the board provided a notice of these reporting requirements.

Chair Kajioka provided that reporting to the board of these settlements is rare. He stated that in 2009/10, the board received 2,331 complaints. Chair Kajioka advised that only 11 complaints were reports under these sections.

Chair Kajioka provided that in 2009, there were approximately 360 million prescriptions filled and dispensed in California by pharmacies. He indicated that the board received notice from patients and from other sources of 307 medication errors during 2009/10. Chair Kajioka stated that this further indicates the high degree of under-reporting under these statutory sections.

Discussion

Ms. Herold provided that the board expects the profession to comply with this reporting requirement.

Chair Kajioka discussed that the reporting is to be done by either the professionals' liability insurer or by the licensee if they do not carry professional liability insurance.

Ms. Shellans provided that the plaintiff's counsel should also file a report with the board. She indicated that the plaintiff should file a report if they did not have representation.

Discussion continued regarding reporting in this area. Concern was expressed regarding the enforcement of this requirement. Chair Kajioka suggested that the board

work with the Department of Insurance on this issue. Dr. Castellblanch recommended that the board also consult the Department of Managed Health Care.

Ms. Herold provided that staff is asking the board for direction on how it would like to proceed with addressing this issue.

No public comment was provided.

3. Update on the Board's Efforts to Implement Components of the Department of Consumer Affairs Consumer Protection Enforcement Initiative

a. Proposed Amendment to 16 California Code of Regulations Section 1762, Regarding Submission of Records to the Board

Chair Report

Chair Kajioka provided an overview on the background of this issue. He stated that beginning in July 2009, the Department of Consumer Affairs has been working with health care boards to improve capabilities to investigate and discipline errant licensees to protect the public from harm. Chair Kajioka indicated that these results yielded the Consumer Protections Enforcement Initiative (CPEI). He explained that the CPEI was comprised of a three pronged solution designed to ensure that investigations were completed and final action taken against a licensee within 12 – 18 months. Chair Kajioka provided that the solution included legislative changes designed to remove barriers to investigations, a new computer system that would meet the board's needs to collect information and monitor performance, and additional staff resources.

Chair Kajioka provided that many of the legislative changes identified by the department were incorporated in SB 1111 (Negrete McLeod). He stated that unfortunately this bill failed passage early in the year during its first policy committee. Chair Kajioka advised that subsequent to that, the department identified provisions in the bill that could be implemented through regulation and encouraged boards to develop language and initiate the rulemaking process.

Chair Kajioka provided that in addition to working with the department on a department wide solution, the board also identified statutory changes that would specifically address pharmacy related issues. He advised that language for these provisions was discussed during the January 2010 Board Meeting, and the board voted to pursue the changes. Chair Kajioka explained that because of the timing with the legislative cycle, these provisions were not pursued this year.

Chair Kajioka provided that more recently, during the June 2010 Board Meeting, the board discussed proposed regulatory language developed by counsel, designed to implement the provisions requested by the department. He stated that the board expressed concern on many of the provisions and with one exception, did not take action on the items.

Chair Kajioka provided that during the October 2010 Board Meeting, board members were advised that the department continues to encourage boards to pursue regulations changes that were previously incorporated into SB 1111. He stated that consistent with this department's request, the board considered several proposed regulation changes.

Discussion

Dr. Castellblanch discussed the upcoming change in administration and questioned whether these provisions are needed considering this change.

Ms. Herold discussed that the board can evaluate whether or not these provisions are good consumer protection policy to advance on its own. She stated that the board can determine at any time that it does not wish to pursue these provisions.

Ms. Shellans requested that the committee consider whether the proposals should be pursued.

The committee evaluated the proposed language (provided below) by each subdivision.

§1762. Unprofessional Conduct Defined

In addition to those acts detailed in Business and Professions Code section 4301, the following shall also constitute unprofessional conduct:

(a) Including or permitting to be included any of the following provisions in an agreement to settle a civil dispute arising from the licensee's practice, whether the agreement is made before or after the filing of an action:

(1) A provision that prohibits another party to the dispute from contacting, cooperating, or filing a complaint with the board; or,

(2) A provision that requires another party to the dispute to attempt to withdraw a complaint the party has filed with the board.

(b) Failure without lawful excuse to provide records requested by the board within 15 days of the date of receipt of the request or within the time specified in the request, whichever is later, ~~unless the licensee is unable to provide the documents within this time period for good cause. For the purposes of this section, "good cause" includes physical inability to access the records in the time allowed due to illness or travel.~~

(c) Failure or refusal to comply with any court order issued in the enforcement of a subpoena, mandating the release of records to the board.

(d) Failure to report to the board, within 30 days, any of the following:

(1) The bringing of an indictment or information charging a felony against the licensee.

(2) The arrest of the licensee.

(3) The conviction of the licensee, including any verdict of guilty, or pleas of guilty or no contest, of any felony or misdemeanor.
(4) Any disciplinary action taken by another licensing entity or authority of this state or of another state or an agency of the federal government or the United States military.

(e) Commission of any act resulting in the requirement that a licensee or applicant registers as a sex offender. The board may revoke the license of any licensee and deny the application of any applicant who is required to register as a sex offender pursuant to Section 290 of the Penal Code or any other equivalent federal, state or territory's law that requires registration as a sex offender.

Discussion – Subdivision (a)
Ms. Shellans reviewed subdivision (a). She stated that this provision would specify that gag clauses in civil suit settlements would constitute unprofessional conduct.

Chair Kajioka offered support to this provision.

No public comment was provided.

MOTION: Recommend to the board to initiate a rulemaking to adopt the proposed text for §1762(a).

M/S: Lippe/Castellblanch

Support: 3 Oppose: 0 Abstain: 0

Discussion - Subdivision (b)
Ms. Shellans reviewed subdivision (b). She stated that this provision would specify that failure without lawful excuse to provide information as requested by the board within 15 days of the receipt of the request or as specified would constitute unprofessional conduct.

Dr. Castellblanch asked why the "good cause" provision was struck from the language.

Ms. Shellans provided that the board indicated at the October 2010 Board Meeting that it was not comfortable with this language.

Mr. Lippe provided that 15 days seems like a short period of time to comply.

Ms. Shellans provided that 15 days is considered adequate time to respond to a subpoena for business records under current California law.

Discussion continued. The committee evaluated an appropriate timeframe for this provision and conditions sufficient to deem "good cause."

Ms. Shellans provided that the intent of the language is to give a broader exemption that can be applied in a case-by-case basis.

Mr. Room discussed that concern has also been expressed regarding board access to records it is not entitled to request. He indicated that the lawful excuse is intended to address this concern.

Public Comment
Steve Gray, representing Kaiser Permanente, discussed that a subpoena is typically negotiated. He stated that lawful excuse would include negotiations.

Ms. Shellans provided that she does not believe lawful excuse is intended to go to negotiation. She stated that this provision is a request for records, not a subpoena.

MOTION: Recommend to the board to initiate a rulemaking to adopt the proposed text for §1762(b).

M/S: Castellblanch/Lippe

Support: 3 Abstain: 0 Oppose: 0

Discussion - Subdivision (c)
Ms. Shellans reviewed subdivision (c). She stated that this provision would specify that failure to comply with a court order or subpoena for records would constitute unprofessional conduct.

Chair Kajioka stated that this is a prudent provision.

No public comment was provided.

MOTION: Recommend to the board to initiate a rulemaking to adopt the proposed text for §1762(c).

M/S: Castellblanch/Lippe

Support: 3 Abstain: 0 Oppose: 0

Discussion - Subdivision (d)
Ms. Shellans reviewed subdivision (d). She stated that this provision would specify that failure to notify the board about an arrest, indictment, conviction or discipline as specified would constitute unprofessional conduct.

Dr. Castellblanch sought clarification regarding the intent for this provision.

Chair Kajioka provided that this provision will ensure a more timely response.

Assistant Executive Officer Anne Sodergren discussed the challenges involved with receiving court documents and arrest records from the respective agencies. She stated that this provision removes this challenge and puts the burden on the licensee.

Mr. Lippe offered a proposal to recommend that the board pursue this provision.

Public Comment
Dr. Gray discussed that he finds subdivision (d)(4) to be ambiguous and broad. He discussed the extensive monitoring system that large organizations would need in order to comply with this provision. Dr. Gray suggested that this language be revised to provide more clarity.

The committee discussed relevant information to be reported to the board including discipline in another state.

Ms. Shellans explained that significant information to be provided to the board includes notification of suspension, restriction, or probation of a license

Ms. Herold discussed the need for the board to be notified of sanctions by the Centers for Medicare and Medicaid Services (CMS) and issues of dishonorable discharge.

Mr. Lippe withdrew his proposal. He offered a second proposal for board staff to rework this language to be brought back for consideration by the committee.

Chair Kajioka suggested the use of “substantially related to the practice of pharmacy” in the revised language.

Ms. Sodergren expressed concern that use of this phrase may leave it to the discretion of the licensee to determine whether or not an action is “substantially related” and is required to be reported to the board.

MOTION: Direct staff to rework the proposed text for §1762(d)(4) for consideration by the committee.

M/S: Lippe/Castellblanch

Support: 3 Abstain: 0 Oppose: 0

Discussion - Subdivision (e)
Ms. Shellans reviewed subdivision (e). She stated that this provision would specify that the board is authorized to revoke a license or deny an application for an act requiring an

individual to register as a sex offender. Ms. Shellans advised that the board has current authority to take disciplinary action for criminal conviction, and as such, this new provision may not be necessary.

The committee discussed the application of this provision and the current California laws that require registration as a sex offender.

Dr. Ratcliff discussed that this provision would provide the board with better ability to take action against a licensee for this conduct.

Mr. Lippe made a proposal to recommend that the board pursue this provision.

Public Comment

Dr. Gray stated that this subdivision seems like an exception to the general rules outlined in the previous provisions.

Ms. Sodergren clarified the intent of this provision. She stated that an act requiring registration as a sex offender would constitute unprofessional conduct.

Dr. Gray suggested that the provision be reworded to clarify this intent.

Ms. Schellans clarified that the fact that a licensees is required to register as a sex offender constitutes unprofessional conduct.

Dr. Gray expressed concern that this area is not substantially related to the practice of pharmacy.

Ms. Shellans provided that this concept derived from the Dental Practice Act which deems a licensee unfit to practice if they are required to register as a sex offender.

Dr. Ratcliff discussed the evolving practice of pharmacy involving more patient contact. He asked the committee to consider whether it is appropriate for a licensee who is required to register as a sex offender to provide an immunization to a child.

Ms. Shellans advised that the penalty for this provision is within the discretion of the board.

Chair Kajioka discussed that this provision would not mandate revocation or specific discipline action and provides the board with flexibility with regards the appropriate penalty imposed.

MOTION: Recommend to the board to initiate a rulemaking to adopt the proposed text for §1762(e).

M/S: Lippe/Kajioka

Support: 2 Oppose: 0 Abstain: 1

4. Discussion and Possible Action to Implement DCA's Recommendations of the Substance Abuse Coordination Committee, Pursuant to SB 1441, for the Pharmacists Recovery Program

Chair Report

Chair Kajioka provided that Senate Bill 1441 created the Substance Abuse Coordination Committee (SACC) and required that this committee, by January 1, 2010, formulate uniform and specific standards in specified areas that each healing arts board must use in dealing with substance-abusing licensees, whether or not a board chooses to have a formal diversion program.

Chair Kajioka provided that to facilitate implementation of these standards, the DCA created a workgroup in 2009 consisting of staff from each of the healing arts boards to draft recommended standards for the SACC consideration during public meetings. He advised that the most recent version of the standards was approved in April 2010, however discussion on standard 4 continues via a subcommittee.

Chair Kajioka referenced to the following 16 standards in their current form.

1. Clinical diagnostic evaluation
   - Specifies that if a licensee in a diversion program or on probation is required to undergo a clinical evaluation it shall comply with :
     i. Qualifications for the licensed practitioner performing the evaluation.
     ii. Acceptable standards for such evaluations.
     iii. Identified elements of the report.
     iv. Timeframes to complete the process and prohibition of the evaluator having a financial relation, etc. with the licensee.
2. Temporary removal of practice for clinical evaluation
   - Specifies that board will issue a cease practice order during the evaluation and review of the results by board staff.
   - Specifies that the licensee will be subject to random drug testing at least two times per week.
   - Sets forth the evaluation criteria that must be considered by the diversion or probation manager when determining if a licensee is safe to return to work and under what conditions.
3. Communication with a licensee's employer, if applicable
   - Requires a licensee to notify the board of the names, physical addresses, mailing addresses and telephone numbers of all employers.
   - Requires a licensee to give written consent authorizing the board and employers and supervisors to communicate regarding the licensee's work status, performance and monitoring.

4. Drug testing
    - Sets forth a minimum testing frequency of 104 random drug tests per year for the first year and a minimum of 50 random drug tests per year (from then on).
    - Specifies that testing shall be observed; conducted on a random basis, as specified; and may be required on any day, including weekends or holidays.
    - Requires licensees to check daily to determine if testing is required and specifies that the drug test shall be completed on the same day as notification.
    - Establishes criteria for the collection sites and laboratories processing the results.
5. Group meeting attendance
    - Sets forth the evaluation criteria that must be considered when determining the frequency of group support meetings.
    - Specifies the qualifications and reporting requirements for the meeting facilitator.
6. Type of treatment
    - Sets for the evaluation criteria that must be considered when determining whether inpatient, outpatient, or other type of treatment is necessary.
7. Worksite monitoring
    - Allows for the use of worksite monitors.
    - Specifies the criteria for a worksite monitor.
    - Establishes the methods of monitoring that must be performed by the worksite monitor.
    - Sets forth the reporting requirements by the worksite monitor; specifies that any suspected substance abuse must be verbally reported to the board and the licensee's employer within one business day; and specifies that a written report must be provided to the board within 48 hours of the occurrence.
    - Requires the licensee to complete consent forms and sign an agreement with the worksite monitor and board to allow for communication.
8. Positive drug test
    - Requires the board to issue a cease practice order to a licensee's license and notify the licensee, employee and worksite monitor that the licensee may not work.
    - Specifies that after notification, the board should determine if the positive drug test is evidence of prohibited use and sets forth the criteria the board must follow when making such a determination.
    - Specifies that if the board determines that it was not a positive drug test, it shall immediately lift the cease practice order.
9. Ingestion of a banned substance
    - Specifies that when a board confirms a positive drug test as evidence of use of a prohibited substance, the licensee has committed a major violation.

10. Consequences for major and minor violations
    - Specifies what constitutes a major violation including: failure to complete a board ordered program or undergo a clinical diagnostic evaluation; treating patients while under the influence of drugs/alcohol, and drug/alcohol related act which would constitute a violation of the state/federal laws, failure to undergo drug testing, confirmed positive drug test, knowingly defrauding or attempting to defraud a drug test.
    - Specifies the consequences for a major violation including: issuing a cease practice order to the licensee; requiring a new clinical evaluation; termination of a contract/agreement; referral for disciplinary action.
    - Specifies what constitutes a minor violation including: untimely receipt of required documentation; unexcused group meeting attendance; failure to contact a monitor when required; any other violations that does not present an immediate threat to the violator or the public.
    - Specifies the consequences for a minor violation including: removal from practice; practice restrictions; required supervision; increased documentation; issuance of a citation and fine or working notice; re-evaluation/testing; other actions as determined by the board.
11. Return to full time practice
    - Establishes the criteria to return to full time practice, including demonstrated sustained compliance, demonstrated ability to practice safely, negative drug screens for at least six months, two positive worksite monitor reports and compliance with other terms and conditions of the program.
12. Unrestricted practice
    - Establishes the criteria for a licensee to request unrestricted practice including sustained compliance with a disciplinary order, successful completion of the recovery program, consistent and sustained participation in recovery activities, demonstrated ability to practice safely and continued sobriety of three to five years, as specified.
13. Private-sector vendor
    - Specifies that the vendor must report any major violation to the board within one business and any minor violation within five business days.
    - Establishes the approval process for providers or contractors that work with the vendor consistent with the uniform standards.
    - Requires the vendor to discontinue the use of providers or contractors that fail to provide effective or timely services as specified.
14. Confidentiality
    - For any participant in a diversion program whose license in on an inactive status or has practice restrictions, requires the board to disclose the licensee's name and a detailed description of any practice restrictions imposed.
    - Specifies that the disclosure will not include that the restrictions are as a result of the licensee's participation in a diversion program.
15. Audits of private-sector vendor
    - Requires an external independent audit every three years of a private-sector vendor providing monitoring services.

- Specifies that the audit must assess the vendor's performance in adhering to the uniform standards and requires the reviewer to provide a report to the board by June 30 of each three year cycle.
- Requires the board and department to respond to the findings of the audit report.

16. Measurable criteria for standards
    - Establishing annual reporting to the department and Legislature and details the information that must be provided in the report.
    - Sets forth the criteria to determine if the program protects patients from harm and is effective in assisting licensees in recovering from substance abuse in the long term.

Discussion
Ms. Herold provided that some of the proposed changes to the disciplinary guidelines would facilitate implementation of portions of these uniform standards.

Dr. Kajoka sought clarification regarding the establishment of the SACC and the subcommittee.

Ms. Sodergren provided that the SACC, comprised of the executive officers of the DCA's healing arts licensing boards, was established by SB 1441 to formulate the standards. She stated that the SACC established a subcommittee of board representatives to develop general parameters for consideration to assist in this process.

No public comment was provided.

5. Discussion Regarding Proposed Modifications to the Board's *Disciplinary Guidelines*

Chair Report
Chair Kajioka provided that California Code of Regulations Section 1760 requires the board to consider disciplinary guidelines when reaching a decision on a disciplinary action. This regulation section was last amended in May 2009.

Chair Kajioka provided that during the October 2010 Board Meeting, the board voted to direct staff to work on updating the Disciplinary Guidelines for the board. He stated that the board has initiated work on identification of proposed changes, many of which have been developed by counsel, but there is still additional work that needs to be done. Chair Kajioka advised that in addition to identifying changes to the language, it is recommended that the guidelines be reorganized.

Chair Kajioka provided that work on the guidelines will continue over the next several months and will be discussed during the next committee meeting for possible action.

Discussion

Mr. Room indicated that the guidelines are a work in progress. He discussed that typically the guidelines are subdivided by license type. Mr. Room suggested that this organization be streamlined to provide one general area for terms and conditions of probation for all license types. He recommended that the board evaluate the guidelines upon further revision.

Ms. Herold discussed the workload involved in this process. She welcomed direction from the committee and stated that the committee can consider the guidelines at a later date as Mr. Room suggested.

Mr. Lippe suggested that a subcommittee be established to assist in this process.

Dr. Castellblanch sought clarification on diversion programs. He asked if there has been any consideration for prevention in this area.

Mr. Lippe provided that the board established the Pharmacists Recovery Program (PRP) for licensees with substance abuse. He stated that the PRP yields positive results.

Ms. Herold provided that the PRP is used as a monitoring program to ensure public safety. She stated that there are currently 75 participants in the program, 30 of which are self referrals. Ms. Herold advised that participants can be terminated from the program for failure to derive benefit or if they have been deemed a public risk.

Dr. Castellblanch expressed concern regarding the current number of PRP participants considering the current population statistics regarding substance abuse.

Ms. Herold indicated that with one exception, all pharmacists who come before the board with a substance abuse program are required to enroll in the program.

No public comment was provided.

Mr. Room ended his conference call with the committee at 3:54p.m.

6. Questions and Answers on the Board's Implementation of 16 California Code of Regulations Sections 1735-1735.8, Pharmacies That Compound, and Sections 1751-1751.8, Pharmacies That Compound Sterile Injectable Medications

Chair Report

Chair Kajioka provided that at the June 2010 Enforcement Committee Meeting, Supervising Inspector Robert Ratcliff provided a question and answer session on the new compounding regulations that took effect in July. He stated that the answers to these and other submitted questions have been compiled into a document. Chair

Kajioka advised that the board is responding to these questions to aid pharmacies in complying with the new requirements.

Chair Kajioka provided that the questions and concerns voiced earlier with the regulations have not occurred since mid-summer.

Chair Kajioka provided an opportunity for new questions to be submitted by the public.

Clarification was requested on several areas. It was suggested that the questions on the document be numbered. The revised Q&A document will be posted on the board's Web site.

Chair Kajioka requested that further questions be submitted in writing to be evaluated by the subcommittee.

7. Discussion Regarding Whether Patients Should Be Allowed to Take Their Multi-Dose Medications Home Upon Discharge From a Hospital

Presentation

Deanne Calvert, JD, representing Sanofi Aventis, discussed the disposal of multi-dose containers of medication ordered for patients in hospitals that are not allowed to go home with patients at discharge because they are not labeled for patient self use. She stated that these multi-dose products include inhalers, eye drops, insulin, and topical creams that are ordered for the patient during a hospital stay but are not in the patient's control while the patient is in the hospital. Ms Calvert advised that because they are not labeled for patient self-use, they are destroyed when the patient is discharged, even though the patient has been charged for the whole product.

Ms. Calvert discussed a project by Spectrum Health, a hospital system in Michigan, which evaluated whether it was feasible to implement a system that would allow patients to take home these medications. She indicated that this project was successful in identifying a generic preprinted label to be added to the patient barcode label that would meet all federal and Michigan state regulations regarding properly labeling medication for dispensing at discharge.

Ms. Calvert discussed outreach efforts for this process in other states and sought input regarding any California laws that would prohibit this process.

Discussion

Chair Kajioka asked who is responsible for the labels.

Ms. Calvert provided that the labeling is completed by a team of hospital pharmacists.

Ms. Herold suggested seeking input from hospitals regarding this process.

Dr. Castellblanch discussed the article regarding this project. He asked whether the authors have any relationship to Sanofi Aventis.

Ms. Calvert provided that she has no knowledge of a relationship. She stated that the article was found in a trade publication and that there was no participation in advance of the publication.

Public Comment
Steve Gray, representing Kaiser Permanente, stated that the waste of medications is a serious issue. He suggested that Ms. Calvert also work with the California Department of Public Health.

8. Provision of the First Ethics Course Pursuant to 16 California Code of Regulations Section 1773.5

Chair Report
Chair Kajioka provided that in mid-November, the Institute for Medical Quality provided the first ethics course for pharmacists under the requirements specified in 16 California Code of Regulations sections1773 and 1773.5. He stated that 12 pharmacists, ordered to complete this course as a condition of their probations, were enrolled. Chair Kajioka provided that the course will follow these individuals over the next 12 months. He advised that periodic reports of the progress of this course will be provided to the committee and board in the future.

Chair Kajioka provided that there is a second course provider interested in providing a course that meets the parameters of section 1773.5; however, the board is not aware that this course has actually been provided or scheduled at this time.

Chair Kajioka provided that whereas the board is not specifically involved in the course provided, as a new program, the board will be kept updated as probationers take and complete these courses.

No discussion or public comment was provided.

9. Review and Discussion of Enforcement Statistics and Performance Standards of the Board

Chair Kajioka referenced the statistics and performance measures provided in the committee packet.

Discussion
Ms. Herold provided that the measures will be posted online effective December 8, 2010. Ms. Herold reviewed the board's timelines. She discussed that the filling of

current staff vacancies will help to improve these timelines as well as to further the board's consumer protection mandate.

No public comment was provided.

10. Public Comment for Items Not on the Agenda

Steve Gray encouraged the committee to address the enforcement of patient consultations as well as the importance of adding the purpose of the medication on the label as a future agenda item.

The meeting was adjourned at 4:59 p.m.

Attachment 9

UNIVERSITY SPECIALTY PHARMACY

September 17, 2010

Virginia Herold, Executive Officer
California Board of Pharmacy
1625 N. Market Blvd., Suite N-219
Sacramento, CA 95834

VIA OVERNIGHT COURIER

RE: RENEWAL OF WAIVER OF CCR TITLE 16, SECTION 1717

Dear Ms. Herold:

We hereby request a renewal of the waiver of California Code of Regulations, title 16, section 1717, subdivision (e), to deliver dispensed Synagis® prescriptions to a licensed home health agency (HHA) for the administration by the HHA to the patient at his/her residence, originally granted to us on November 26, 2007 (and subsequently clarified on January 12, 2008) via a letter from you (a copy of which is attached for your reference).

As before, we would like to note the following highlights of our proposed program:

1. The medication involved (*Synagis*®) requires refrigeration, and as a result, must at all times be stored either in a refrigerator or in a cooler to maintain its integrity. By allowing these medications to be delivered to the administering professional nurses rather than direct delivery to patients, better control can be maintained, avoiding the accidental and unattended delivery of the drugs (e.g. being left on a doorstep) and the mishandling of the subject drugs once in the residence.

2. Transportation of the prescriptions to the designated nurses will be either delivery driver or via overnight courier. The nurses will, in turn, directly deliver the prescriptions to the patients' homes upon receipt. At all times following its delivery, the prescribed medication will be under the direct supervision of the nurse(s) who receive it.

3. If consultation is needed regarding the delivered prescriptions, it will be available primarily through written drug information (provided in English and Spanish) and a pharmacist will be available at all times for further consultation via phone.

Although we understand that a waiver of the type we are requesting an extension on is extraordinary and unique, there is precedent for such waiver under similar circumstances, and our successful service of thousands of patients during the course of the previous waiver demonstrates its value and a record of otherwise legally-compliant service thereunder. It is imperative to the success of our service of the State's most under-serviced patients that we obtain this waiver. Medi-Cal families are often at the highest risk for adulteration of these delivered medications, and at similarly high risk for contracting RSV if this medication is *not* properly maintained and administered.

The season for Synagis commences in late October/early November, and patient intake picks up sharply in the month prior to the start of the season. We expect that the majority of the infants we will service will be dosed in their homes, so the receipt of the subject waiver becomes of paramount importance to this program in the coming year.

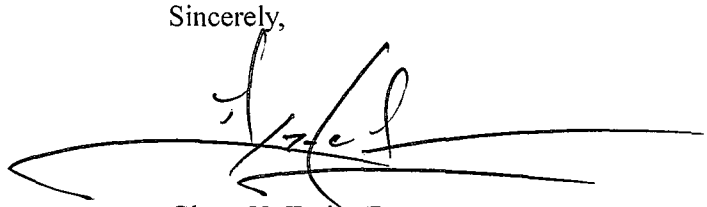
We have successfully developed a web-based patient information system which has given referral sources unprecedented real-time access to patient status, and the State a way of accessing overview statistics on demand.

3328 Garfield Avenue, Commerce, CA 90040 Phone: (323) 201-4488, (866)SYNAGIS
Facsimile: (866) 728-4810

While we pray for an extension without another appearance before the Board, we would be more than happy to appear again to defend this request at the October meetings. Additionally, if there is anything I can do to help expedite the waiver renewal process for our pharmacy, or if I may be of assistance in any way, please don't hesitate to contact me.

We look forward to continuing to work with you and the entire staff at the California Board of Pharmacy in the service of some of the State's most precious patients.

Sincerely,



Glenn H. Truitt, Esq.
General Counsel

Enclosure

cc: Bob Ratcliff, Pharm.D., Supervising Inspector
Scot Silber, R.Ph., President/CEO
Scott Schumaker, COO
Doug Cammann, R.Ph., General Manager
Shawn Silber, General Manager, USP

California State Board of Pharmacy
400 R Street, Suite 4070, Sacramento, CA 95814
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www.pharmacy.ca.gov

STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

January 12, 2008

Glenn H. Truitt, Esq.
Chief Operating Officer/General Counsel
University Specialty Pharmacy
2108 Magnolia Boulevard, Suite B
Burbank, CA 91506

Second letter: Correction of November 26, 2007 Letter

Dear Mr. Truitt:

This letter is an clarified response to your request for University Specialty Pharmacy to obtain a waiver from board regulations to provide Synagis prescription medicine to a licensed home health Agency for administration by the home health agency to a patient at his or her residence. The specific request involves a waiver from 16 California Code of Regulations section 1713(a) under the waiver authority specified in 1713(b).

You appeared at the October 24, 2007 Board of Pharmacy Meeting to make this request directly to the board.

This letter serves as formal notice to you of the board's actions:

> For a three-year period, from December 1, 2007 until January 1, 2011, University Specialty Pharmacy is granted a waiver from 16 California Code of Regulations section 1713(b), to permit the delivery of Synagis to home health care patients via a nurse.

Please do not hesitate to contact me with questions at (916) 574-7911.

Sincerely,

VIRGINIA K. HEROLD
Executive Officer

Attachment 10

California State Board of Pharmacy and Medical Board of California

Guidelines for Transmission and Receipt of Electronic Controlled Substance Prescriptions

Pursuant to DEA Interim Final Rule (IFR): Electronic Prescriptions for Controlled Substances
21 CFR Parts 1300, 1304, 1306, and 1311 (Fed. Reg. 16236-16319 (March 31, 2010))
Effective June 1, 2010

Deputy Attorney General Joshua A. Room and Deputy Attorney General Kerry Weisel

The following is merely a summary and/or paraphrasing of the law as reflected in the IFR, and/or a compilation of opinion(s) on the interpretation of the IFR. It does not constitute an official opinion of, nor is it sanctioned by, the Attorney General, the California State Board of Pharmacy, or the Medical Board of California. This is not a binding statement of pertinent law. It is a summary, and is not intended to be comprehensive. It is offered as a guideline and a compilation of references to the appropriate sections of the IFR. Any person(s) wishing to understand the IFR are encouraged to review the regulation(s) themselves, and/or to consult an attorney.

California State Board of Pharmacy and Medical Board of California
Guidelines for Transmission and Receipt of Electronic Controlled Substance Prescriptions
Pursuant to DEA Interim Final Rule (IFR): Electronic Prescriptions for Controlled Substances
21 CFR Parts 1300, 1304, 1306, and 1311 (Fed. Reg. 16236-16319 (March 31, 2010)) – **effective June 1, 2010**

Who is affected: Prescribers; pharmacies; application providers. To participate, each category must:

Prescribers	Pharmacies	Application Providers
Select application and ensure it meets DEA requirements	Select application and ensure it meets DEA requirements	Evaluate application(s) and/or reprogram as necessary
Apply for identity proofing	Set access controls	Undergo third-party audit or certification of software
Set access controls	Process prescriptions	Make audit/certification report available to users/possible users
Sign (and archive) prescriptions	Archive prescriptions	

Participation is voluntary.[1] The regulations do not mandate that prescribers use only electronic prescribing for controlled substances, nor do they require pharmacies to accept electronic controlled substance prescriptions.[2] Written prescriptions are still acceptable, as are oral prescriptions for Schedule III-V controlled substances. But electronic prescriptions for controlled substances (Schedule II-V) must meet DEA regulatory requirements.

Audit and Selection of Software Application(s)

Before being used to create, sign, transmit, or process controlled substance prescriptions, electronic prescription applications or pharmacy applications (stand-alone or integrated Electronic Medical Record (EMR) types) must have a third-party audit of the application certifying that it meets the requirements of the DEA regulations. This audit may be conducted by (1) a person/entity qualified to conduct a SysTrust, WebTrust, or SAS 70 audit; (2) a Certified Information System Auditor who performs compliance audits; or (3) A certifying organization whose certification process has been approved by the DEA.[3] (21 CFR § 1311.300.) This is a provider responsibility.

The auditor issues a report and/or certification to the application provider. The application provider must keep that report and/or certification for two years, and make it available to any prescriber or pharmacy that uses the application or is considering using the application. (21 CFR § 1311.300(f).) May be on provider's website.

Prescribers and pharmacies must review audit/certification report prior to using application to confirm that it performs the appropriate functions successfully. (21 CFR §§ 1311.102(d), (e), 1311.200(a), (b).) A prescription created using an application that does not meet requirements is invalid. (21 CFR § 1311.100(d).)

[1] There are various incentives for electronic prescribing and use of electronic medical records (EMR), most notably those contained in the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), and the Health Information Technology for Economic and Clinical Health (HITECH) Act, a component of the American Recovery and Reinvestment Act of 2009 (ARRA). These federal laws include incentive payments under Medicare for prescribers who reach certain e-prescribing and/or EMR thresholds. Prescribers may receive incentive payments on their billings of up to 2% in 2009 and 2010, 1% in 2011 and 2012, and 0.5% in 2013; they may be hit with penalties of 1% in 2012, 1.5% in 2013, and 2% in 2014 and beyond, for failure to meet these e-prescribing/EMR thresholds.

[2] Beginning January 1, 2012, Medicare Part D prescriptions can no longer be sent to a pharmacy by computer-generated fax. As of this date, prescriptions must be (a) transmitted electronically, (b) handed to the patient in hardcopy form, or (c) manually faxed to the pharmacy. As of October 1, 2008, CMS required that all written Medicaid prescriptions be written on a tamper-resistant (secure) prescription blank. Electronic prescriptions are excluded from this requirement (and are therefore acceptable for Medicaid).

[3] A follow-up audit/certification must be conducted whenever functionality related to controlled substance prescription requirements is altered, or every two years, whichever comes first. (21 CFR § 1311.300(a)(2), (e)(2).)

Furthermore, both prescribers and pharmacies have an **ongoing responsibility** to immediately cease using an application (and ensure that any designated agents also cease using the application) if: any required functions of the application are disabled or appear to be functioning improperly; the application provider notifies them that a third-party audit or certification report indicates that the application no longer meets DEA requirements; or the application provider reports that the application is non-compliant. (21 CFR §§ 1311.102, 1311.200, 1311.300.)

The requirements for an electronic prescription application are quite specific. (21 CFR § 1311.120.)

Identity Proofing of Prescribers (Practitioners)[4]

Identity proofing is the process by which a prescriber is uniquely identified, so that only that prescriber has the access necessary to authorize and sign electronic prescriptions using a software application. Identity proofing of prescriber must be done by an approved credential service provider (CSP) or certification authority (CA) [for digital certificates]. Remote identity proofing is permissible. (21 CFR § 1311.105.) Prescribers should consult with their selected application provider to determine which identity proofing organization to work with.

Institutional prescribers can undergo identity proofing using the third-party method or identity proofing can be conducted in-house by their institution(s). (21 CFR § 1311.110.)

Once identity is verified, the prescriber is issued a two-factor authentication credential. (21 CFR § 1311.105.) The two factors must be two of the following: (1) Something the prescriber knows, such as a password or PIN; (2) A hard token separate from the computer being accessed (meeting at least FIPS 140-2 Security Level 1); or (3) A biometric, such as a fingerprint or iris scan, meeting DEA criteria. (21 CFR. §§ 1311.115, 1311.116.)

Two-factor credentials will be used for (1) approving access controls, and (2) signing electronic prescriptions. (21 CFR § 1311.120.) They must always be in the exclusive control of the prescriber. (21 CFR § 1311.102.)

Access Controls – For Both Prescribers and Pharmacies

Access controls relate to software-based specifications and restrictions that ensure that only those individuals authorized to sign prescriptions are allowed to do so, and only those persons authorized to enter information regarding dispensing, or to annotate or alter or delete prescription information, are allowed to do so.

At the prescriber level, in each registered location there must be at least two individuals designated to manage access control to the application. One of these has to be the registered prescriber who has obtained two-factor authentication credentials. (21 CFR § 1311.125.) These access controls are required to limit the permission to sign controlled substance prescriptions to persons whose DEA registration is current and in good standing, and whose state authorization(s) to prescribe are current and in good standing,. (21 CFR § 1311.125(b).) There is also a two-person management requirement in an institutional setting. (21 CFR § 1311.130.)

Prescriber software application must be capable of setting logical access controls to limit permissions for both the indication that a prescription is ready for signing, and the electronic signature on the prescription, as well as for changes to the access controls themselves. (21 CFR § 1311.120(b).) The software must revoke permission to sign controlled substance prescriptions on the date that any of the following is discovered: A hard token or any other authentication factor is lost, stolen or compromised; DEA registration expires without renewal; DEA registration is terminated, revoked, or suspended; or the prescriber is no longer authorized to use the software (e.g., when the prescriber leaves the practice or institution). (21 CFR §§ 1311.125(d), 1311.130(d).)

At the pharmacy level, logical access controls in the pharmacy application must be set so that only the person(s) authorized to enter information regarding dispensing of controlled substance prescriptions and/or to annotate or alter or delete records of prescriptions, are permitted to do so. (21 CFR §§ 1311.200(e), 1311.205(b)(1), (2).)

[4] "Practitioner" is used throughout the regulations where we might use "prescriber." We use prescriber exclusively in this document.

Signature and Transmission of Prescription(s) by Prescribers

A prescriber or prescriber's agent may prepare one or more prescriptions for review and signature by prescriber. (21 CFR § 1311.135(a).) A prescriber may access a list of prescriptions for a single patient, and sign one, some, or all of them at once. (21 CFR § 1311.140(a)(1).) The screen must display, for each prescription: the date of issuance; full patient name; drug name; dosage strength and form; quantity prescribed; directions for use; refills authorized (for Schedule III-V drugs); earliest fill date, if applicable (see 21 CFR § 1306.12(b)); and the name, address, and DEA registration number of the prescriber. (21 CFR § 1311.140(a)(1), 1311.120(b)(9).) The same screen must also display the following statement: "By completing the two-factor authentication protocol at this time, you are legally signing the prescription(s) and authorizing the transmission of the above information to the pharmacy for dispensing. The two-factor authentication protocol may only be completed by the practitioner whose name and DEA registration number appear above." (21 CFR § 1311.140(a)(3).)

Only the prescriber may indicate those prescriptions that are ready to be signed and, while the screen displays the prescription information and the warning statement, only the prescriber may be prompted to complete, and may complete, the two-factor authentication protocol. Completion of the two-factor authentication protocol by the prescriber is a legal signature pursuant to 21 CFR § 1306.05. (21 CFR § 1311.140(a)(2), (4), (5).) Multiple prescriptions for the same patient can be signed by one application of the two-factor authentication protocol; no separate keystroke is required to acknowledge the warning or to sign the prescription. (21 CFR § 1311.140.)

Upon completion of the two-step authentication protocol, one of two things must happen: either the application digitally signs (i.e., locks) and electronically archives the required information (21 CFR § 1311.140(a)(6)), and designates the prescription eligible for transmission; or, if the prescriber has a digital certificate (see 21 CFR § 1311.105), the application applies the prescriber's private key to digitally sign and electronically archive the required data (21 CFR § 1311.145) before designating the prescription for transmission. If the latter, digital certificate methodology is applied, the prescription may be transmitted to a pharmacy without digital signature, and a digital signature is not required, so long as the application first checks the certificate revocation list of the prescriber's issuing certificate authority (CA) prior to transmission. (21 CFR § 1311.145(e), (f), (g).)

The prescription must be transmitted as soon as possible after signature. (21 CFR § 1311.170(a).) It must stay in electronic form all the way from the prescriber to the pharmacy (including through intermediaries); at no time may it be converted to another form (e.g., facsimile). (21 CFR § 1311.170(f).) Likewise, the application must restrict printing of electronic prescriptions for controlled substances. The application must not allow electronic transmission of a prescription that has already been printed. (21 CFR § 1311.170(d).) A prescription may be printed **after** its electronic transmission only under two circumstances: (a) where the prescriber is notified by an intermediary or pharmacy that an electronic prescription was not delivered, in which case the prescriber must be sure that any paper (or oral) prescription issued as a replacement indicates that the prescription was previously transmitted electronically, to a particular pharmacy, and that transmission failed; or (b) where a prescriber prints a copy of an electronically-transmitted prescription (or a list of a patient's prescriptions), and the copy or list is clearly labeled "Copy only – not valid for dispensing." (21 CFR § 1311.170(c).) Data from prescription(s) may also be electronically transferred to (electronic) medical records. (21 CFR § 1311.170(c).)

It is no longer required that the prescription be transmitted immediately. The DEA has expressly acknowledged that prescribers "may prefer to sign prescriptions before office staff add pharmacy or insurance information." (General Questions and Answers [as of 03/31/2010], www.deadiversion.usdoj.gov/ecomm/e_rx/faq/faq.htm.) In other words, a (reasonable) delay between signature and transmission is permissible, and it is also acceptable for additions or changes to be made to items in the information being electronically transmitted that are not part of the prescription information required by DEA regulations under 21 CFR Part 1306. However, the contents of the prescription required by Part 1306 must not be altered either following signature or during transmission, not by the prescriber, prescriber's staff, or intermediaries. (21 CFR § 1311.170(e).) The data may be converted to be readable in or by different softwares and so forth, but Part 1306 data may not be changed. (*Ibid*.)

Receipt and Processing of Prescription(s) by Pharmacies

The pharmacy application must be certified by the third-party auditor to, among other things: import, store, and display the information required for prescriptions; import, store, and display an indication of signing transmitted by the prescriber; import, store, and display the number of refills; and import, store, and verify the prescriber's digital signature, where applicable. (21 CFR § 1311.200(a)(1), (2), (3), (4).) The second and the fourth of these listed requirements are particularly important to a pharmacy's proper verification of transmitted prescriptions.

Namely, when a pharmacy receives a transmitted electronic prescription, it must either: (a) have been digitally signed by the last intermediary that sends the prescription record to the pharmacy, in which case the digitally signed record must be archived upon receipt (21 CFR §§ 1311.205(b)(3), 1311.210(b)(1)); (b) have been signed digitally using the prescriber's digital certificate, in which case the pharmacy application must verify the digital signature as provided in FIPS 186-3, check the validity of the digital certificate against the certificate revocation list of the issuing certificate authority (CA), and archive the digitally signed record as well as an indication that it was verified upon receipt (21 CFR § 1311.210(c)); or (c) be digitally signed (as per 21 CFR § 1311.205(b)(4)) and archived by the pharmacy upon receipt (21 CFR §§ 1311.205(b)(3), 1311.210(a)(2).) Pharmacists are (still) permitted to annotate an electronic prescription in the same way they would a paper prescription, except that the annotations must be made and retained electronically. (21 CFR § 1311.200(f).) The IFR also permits transfers between pharmacies of electronic prescription information for Schedule III-V controlled substances for refill(s) on a "one-time basis only," so long as the transfer is communicated directly between two licensed pharmacists, and appropriate notations are added to the prescription record at both the transferring and receiving pharmacy. Pharmacies that electronically share a real-time, online database may (also) transfer up to the maximum refills permitted by law and the prescriber's authorization. (21 CFR § 1306.25(a), (b).)

When a pharmacist receives a paper or oral prescription that indicates that it was previously transmitted to that pharmacy electronically, the pharmacist must check the pharmacy's records to ensure that the electronic version of the prescription was not received and (already) dispensed. If both versions were received, the pharmacist must mark one as void. (21 CFR § 1311.200(g).) When a pharmacist receives a paper or oral prescription that indicates that it was previously electronically transmitted to a different pharmacy, the pharmacist must check with the other pharmacy to determine whether the prescription was (already) received and dispensed. If the electronic transmission version was already received and dispensed, the subsequent paper (or oral) prescription must be marked as void. If the electronic transmission version has not yet been dispensed, that version must be marked as void and the paper (or oral) prescription may be dispensed. (21 CFR § 1311.200(h).)

Archiving of Prescription(s) Recordkeeping by Prescribers and Pharmacies

As has been indicated above, the prescribing application is required to archive the prescription at the time that it is signed, and the pharmacy application is required to archive the prescription at the time it is received (so that the two archived versions can later be compared to ensure there has been no alteration of prescription contents required by Part 1306). (21 CFR §§ 1311.140(a)(6), 1311.145, 1311.205(b).) In addition to storing the data required by Part 1306 and by 21 CFR § 1311.205, pharmacy applications must be capable of sorting/retrieving controlled substance prescriptions by prescriber name, patient name, drug name, and date dispensed. (21 CFR § 1311.205(b)(11), (12).) The records must be secure, maintained electronically, backed up daily, and able to be read or downloaded into human-readable format. (21 CFR §§ 1311.205(b)(17), (18), 1311.305.)

The prescriber's electronic prescription application must generate a log of all controlled substance prescriptions issued by the prescriber during the previous calendar month and must provide that log to the prescriber no later than seven calendar days after month's end. (21 CFR § 1311.120(b)(27)(i).) In addition, the application must be capable of generating a log of all controlled substance prescriptions issued by the prescriber during a time period specified by the prescriber, upon request; it must be able to search back for at least the previous two years. (21 CFR § 1311.120(b)(27)(ii).) Any logs that are generated must be archived, human-readable, and sortable by patient name, drug name, and issuance date. (21 CFR § 1311.120(b)(27)(iii), (iv), (v).)

Audit Trails and Other Requirements

The regulations specify various events and incidents for which both prescriber and pharmacy applications must maintain an audit trail (i.e., a secure activity log that can be used to retrace those events/incidents). An "audit trail" is defined as "a record showing who has accessed an information technology application and what operations the user performed during a given period." (21 CFR § 1300.03.)

For prescribers, the application must track, among other things, the creation, alteration, indication of readiness for signing, signing, transmission, or deletion of an electronic controlled substance prescription, as well as any notification of a failed transmission. (21 CFR § 1311.120(b)(23).) For pharmacies, the application must track, among other things, all receipts, annotations, alterations, and deletions of controlled substance prescriptions. (21 CFR § 1311.205(b)(13)(i).) For both prescribers and pharmacies, the application(s) must track: the setting of, or changes to, access controls (21 CFR §§ 1311.120(b)(23)(ii), 1311.205(b)(13)(ii)); as well as other events that the application provider establishes as "auditable events," which are typically security incidents (21 CFR §§ 1311.120(b)(23)(iv), 1311.205(b)(13)(iii), 1311.150(a), 1311.215(a).)

In addition, both types of applications must conduct daily internal audits to determine whether any "auditable events" (security incidents) have occurred on that day. (21 CFR §§ 1311.150, 1311.215.) This may be an automated function that generates a report for the prescriber or pharmacist to review. If the prescriber or pharmacist reviewing the report determines that a security incident has in fact occurred, that incident must be reported to the application provider and to the DEA within one day. (21 CFR §§ 1311.150(c), 1311.215(c).)

Relationship Between DEA Regulation(s) and California Law

The IFR packet issued by the DEA contains the following statement: "This rulemaking does not preempt or modify any provision of State law; nor does it impose enforcement responsibilities on any State; nor does it diminish the power of any State to enforce its own laws." (VII. Required Analyses, G. Executive Order 13132, Fed Reg. 16304.) The DEA has also been explicit in the FAQs on its website that "electronic prescriptions for controlled substances may be subject to state laws and regulations," and that "[i]f state requirements are more stringent than DEA's regulations, the state requirements would supersede any less stringent DEA provision." (Interim Final Rule with Request for Comment, Questions and Answers for Pharmacies [as of 03/31/2010], www.deadiversion.usdoj.gov/ecomm/e_rx/faq/pharmacies.htm.) Thus, any conflicting state laws (e.g., about five states prohibit controlled substance electronic prescriptions altogether, and a further twenty or so do not permit electronic prescribing of Schedule II drugs) are apparently permitted to control. The IFR is also explicit that the two-year retention period prescribed by the IFR does not preempt any longer retention period required by state (or other federal) law or regulation. (21 CFR § 1311.205(b).

As to this last point, because the requirement in California is that all records of manufacture, sale, acquisition, or disposition, and/or all prescription records, be maintained and kept available for inspection for three years (Bus. & Prof. Code, §§ 4081, 4333; Cal. Code Regs., tit. 16, § 1717), the three-year retention period applies. (See also Health & Saf. Code, §§ 11159, 11159.1 [seven year retention for chart orders].) California standards for transfers of electronic prescriptions between pharmacies also control. (Cal. Code Regs., tit. 16, § 1717.)

In general, however, California is one of the most "e-prescribing-friendly" states, and state law does not set up any obstacles to electronic prescribing of controlled substances (or dangerous drugs). California law (Bus. & Prof. Code, § 4040, Health & Saf. Code, § 11027) defines "prescription" to include "electronic transmission." And California requirements for electronic transmission of prescriptions (Cal. Code Regs., tit. 16, §1717.4) do not materially increase the burden for electronic prescribing over the DEA requirements.[5] California law even specifically permits electronically transmitted prescriptions to be stored only in electronic form (i.e., they do not have to be printed/reduced to writing) so long as that storage is tamper-proof. (Bus. & Prof. Code, §4070.)

[5] Under California law, an electronically transmitted prescription shall include, in addition to the name and address of the prescriber, a prescriber telephone number, the date of transmission, and the identity of the recipient. (Cal. Code Regs., tit. 16, § 1717.4(c), (d).)

In some ways, California law would make it easier to electronically transmit controlled substance prescriptions than does the federal regulation. For instance, California law would allow a prescriber, prescriber's agent, or pharmacist to direct-enter prescriptions (via remote access) into a pharmacy or hospital computer (with the approvals required by Health and Safety Code section 11164.5), and would allow various other healthcare licensees (who may or may not themselves be prescribers) acting as consultants to certain licensed facilities to electronically transmit Schedule III-V prescriptions. (Bus. & Prof. Code, §§ 4071.1, 4072.) However, at least the "direct entry" methodology is reliant on allowance by DEA regulations, and since this is not permitted by the IFR, remote access direct entry of controlled substances is not permitted. (Bus. & Prof. Code, § 4071.1; Health & Saf. Code, § 11164.5.) As for the allowance under California law for non-DEA registrants to be able to authorize controlled substance prescriptions on behalf of licensed facilities, that is likewise in doubt.

Other Miscellaneous Information

Surescripts has generated lists of software providers for both prescribers and pharmacies that are "certified" to provide the services necessary for various aspects of electronic prescribing. The list includes both stand-alone and EMR (electronic medical record) software platforms, and includes information on whether the software is capable of providing prescription benefit (formulary) functions, medication history, and prescription routing. The list can be found at www.surescripts.com/certified. Surescripts also has a list of "Gold Solution Providers" for prescriber software vendors, and is a sponsor of the website www.getrxconnected.org, which is primarily a tool for prescribers to learn the benefits of e-prescribing and the steps necessary for them to participate.

Attachment 11

Evaluation of Home-Generated Pharmaceutical Programs in California

CalRecycle Background Paper
for July 20, 2010 Workshop

Issued July 12, 2010

Revised January 19, 2011

Contents

Foreward

A background paper was originally released for a CalRecycle pharmaceutical drug waste disposal program workshop held in July 2010 (http://tinyurl.com/July2010PharmaWrkshop) as part of a process to develop a report to the legislature, mandated by California's Senate Bill 966 (Simitian, Chapter 542, Statutes of 2007). This updated version of the background paper incorporates new information and some comments from stakeholders. The primary changes in this report are:

- *Explanation of current statutory and regulatory authority;*
- *Revised analysis of "Program Survey and Results" including updated information on cost effectiveness;*
- *Additional information on potential illegal diversion of collected drugs;*
- *Expanded "Overview of Programs Outside of California"; and*
- *Grouping of "Potential Options for Further State Actions" into regulatory options and funding options. Note that this section was and remains intended to provide information for discussion purposes only. It does NOT include any CalRecycle recommendations regarding these options.*

To guide readers, for sections with more significant changes, a note in italics at the beginning of selected sections describes the type of changes incorporated in that section.

I. Introduction

1. Senate Bill 966 (SB 966)

Enacted in 2007, Senate Bill 966 (Simitian, Chapter 542, Statutes of 2007) addresses improper disposal of pharmaceutical waste into sewer systems, which results in pharmaceuticals entering waterways and drinking water. The goal of SB 966 is to establish a program through which the public may conveniently return drugs for safe and environmentally sound disposal.

SB 966 directed the California Integrated Waste Management Board, which is now the California Department of Resources Recycling and Recovery (CalRecycle), to:

1. Establish criteria and procedures for model collection programs by December 2008

   CalRecycle worked closely with numerous agencies, including the California Department of Public Health (CDPH), the Department of Toxic Substances Control (DTSC), the State Water Resources Control Board (SWRCB), and the California State Board of Pharmacy (CBOP), and considered stakeholder input to develop criteria and procedures for model pharmaceutical waste collection programs. CalRecycle adopted Model Guidelines in November 2008, with a subsequent revision in February 2009. Programs are not required to follow these Model Guidelines but they must be consistent with them in order to be considered a model program under SB 966.

2. Evaluate model collection programs in California

   CalRecycle sent surveys to all known programs that collect home-generated pharmaceuticals in California. This paper presents the results of these surveys.

3. Report to the Legislature by December 2010

   As required by SB 966, CalRecycle will include the following components:

   - An evaluation of the model programs for efficacy, safety, statewide accessibility, and cost effectiveness;
   - Consideration of the incidence of diversion of drugs for unlawful sale and use, if any; and
   - Recommendations for the potential implementation of a statewide program and statutory changes.

2. Purpose of Background Paper

This paper served as a basis for discussion at the July 20, 2010, "California's Model Drug Collection Program Workshop" and it served as foundational material as CalRecycle prepared the required report to the Legislature. This material was intended to stimulate discussion and input from stakeholders and affected parties.

This paper includes:

- **Program Surveys and Results (Section II)**: Identifies the types and number of home-generated pharmaceutical waste collection programs in California, the number that meet the Guidelines for model programs within each type, and an evaluation of programs based on the four factors in SB 966 (safety, statewide accessibility, cost effectiveness and efficacy);
- **Challenges and Barriers (Section III)**: Outlines some of the challenges to program implementation;
- **Overview of Programs Outside of California (Section IV)**: Covers a range of programs in other countries and states; and,
- **Potential Options for Further State Action (Section V)**: Discusses preliminary analysis of potential options for state action.

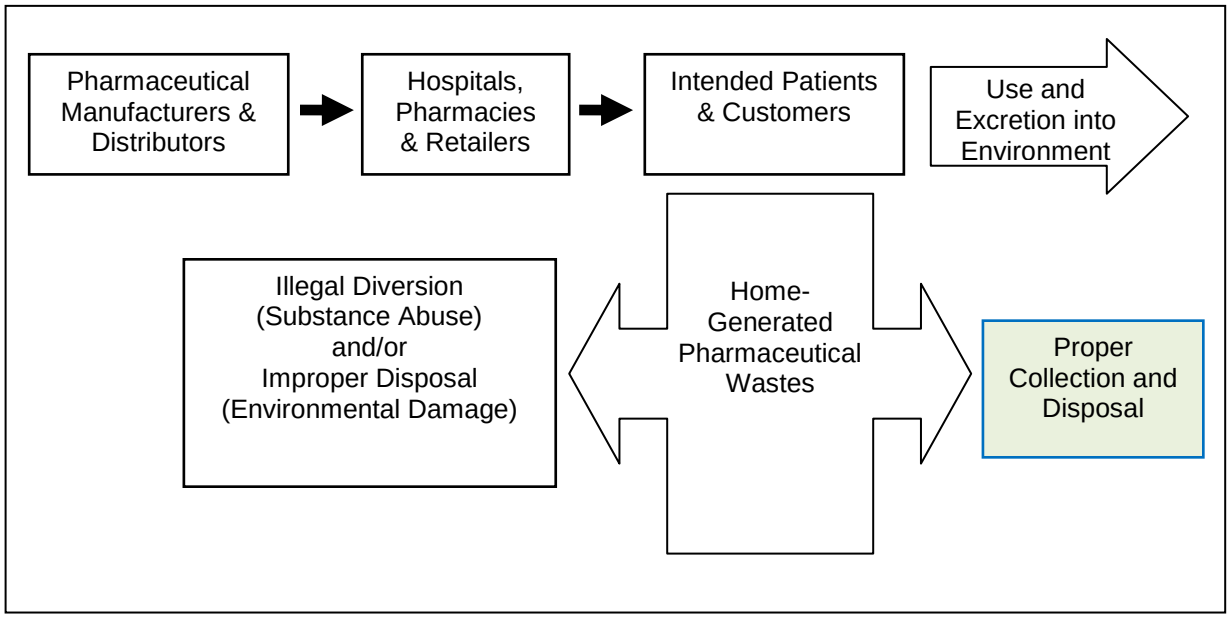
Several topics not within the direct scope of this analysis but related to the topic are listed below. While some topics are discussed when necessary as they relate to the collection programs, the paper does not discuss all topics in detail:

- Excretion. While human excretion is a major pathway for pharmaceuticals to reach the environment, it is a separate problem from unused pharmaceuticals that become home-generated waste. The latter issue, home-generated waste, is the focus of this paper.
- Drug Distribution Solutions. While fewer prescriptions, reduced sales of pharmaceuticals, or changes resulting in more complete usage of medications could result in a lower amount of home-generated pharmaceuticals, these actions would occur before pharmaceuticals become home-generated waste.
- Controlled Substances. SB 966 specifically states that it does not apply to controlled substances; however, they are mentioned in this paper because their special requirements impact collection programs for other home-generated pharmaceutical wastes.
- Reverse Distributors. Reverse distributors collect unused and expired medication from hospitals and pharmacies and in return provide monetary credit or disposal of that waste. This activity occurs before pharmaceuticals become home-generated waste. In addition, several concerns exist regarding applying this concept to home-generated wastes.[*]

Figure 1 shows a simplified view of the flow of pharmaceuticals, including both prescription medications and non-prescription (over-the-counter) medications.

[*] Once dispensed, medications may be tampered with, kept in inappropriate conditions, and become unfit for redistribution. According to the California Board of Pharmacy, a reverse distributor may not accept previously dispensed medicine and may not have sufficient safety standards to prevent illegal drug diversion.

Figure 1. Simplified Flow of Pharmaceuticals



This paper only deals with one aspect of the life cycle of pharmaceuticals, specifically the post-consumer fate of unused pharmaceuticals that become home-generated pharmaceutical waste. This paper discusses current efforts and future options to properly collect and dispose of this home-generated pharmaceutical waste in ways that minimize illegal diversion (potentially leading to substance abuse) and improper disposal (potentially leading to environmental damage).

3. Home-Generated Pharmaceuticals in California

Based on information available to CalRecycle, collection programs in California collect approximately 200,000 pounds of home-generated pharmaceutical waste per year. These collection programs appear to be quite safe with very low illegal diversion. Out of 256 collection sites or programs representing 86 percent of all known programs operating in California, a CalRecycle survey found that in the past 15 years there were no reported signs of illegal drug diversion (see Section III, *1. High Cost of Safe Collection*).

However, these programs likely collect a small percentage of all home-generated pharmaceutical waste, although there is not a definitive estimate of the amount of home-generated pharmaceutical waste in the state. Several sources suggest that a very large amount is sold and that a significant percentage subsequently becomes waste in California:

- In California pharmacies, the total retail sales for filled prescription drugs in 2009 (not including over-the-counter drugs or mail order prescriptions) reached nearly $19 billion for more than 300 million prescriptions.[1]
- The Associated Press estimated that Americans generate at least 250 million pounds of pharmaceuticals and contaminated packaging in medical facilities each year.[2] Relative to California population, that would be approximately 30 million pounds in California hospitals alone.

- Some estimates suggest that 10 percent to 33 percent of all pharmaceuticals go unused.[3] There is not universal agreement on these percentages, with some studies reporting as little as 3% unused while others report that 50% or more are unused.[4]
- In addition, the number of prescriptions per 100 people has increased between 1995 and 2008 from 0.8 to 1.2 nationwide.[5] Considering our aging population, this trend is likely to continue.

Meanwhile, there is growing concern about illegal diversion of pharmaceuticals from homes. Collection programs provide a safe, legal, and environmentally preferable means to managing unwanted drugs from residences where they can be abused. This is a driving force for establishing home-generated pharmaceutical collection programs.

4. Current Status of Regulations, Statutes, and Policy

In California, current statutory and regulatory authority to govern collection and disposal of home-generated pharmaceutical waste is divided amongst several state and federal entities. This division leads to confusing roles, responsibilities and program requirements, and is an underlying issue that challenges collection program administrators. For example:

- The U.S. Drug Enforcement Administration (DEA) governs the collection and disposal of controlled substances, a subset of home-generated pharmaceuticals, which requires law enforcement to oversee these activities;
- The California Board of Pharmacy (CBOP) licenses pharmacies, but currently does not explicitly authorize pharmacies to accept the return of home-generated pharmaceuticals, yet it supports Model Guidelines that allow collection following certain practices;
- The California Department of Toxic Substances Control (DTSC) regulates hazardous waste, which may include some pharmaceutical waste, while exempting home-generated pharmaceutical waste from classification as hazardous waste;
- The California Department of Public Health (CDPH), through the Medical Waste Management Act (MWMA), regulates collection and disposal of medical waste in California. However, it does not have statutory authority to regulate collection and disposal of home-generated pharmaceutical waste, which is excluded from the definition of medical waste. Instead, it applies a best management policy for collecting this waste. CDPH interprets this policy as follows: if home-generated pharmaceutical waste is consolidated with other home-generated pharmaceutical waste from different residences or is handled by a third party, then it is no longer considered home-generated but rather consolidated medical waste and the MWMA regulations apply, requiring the waste to be handled as medical waste.

Many stakeholders identified possible alternatives for revising the current statutes, regulations and policies to address confusion about roles and responsibilities and facilitate new take-back programs. It should be noted there is no consensus among stakeholders on roles and responsibilities and without clear legislative direction and state agency authority over certain tasks, confusion will continue.

II. Program Surveys and Results

Note: In response to comments on the Background Paper for the July 2010 stakeholder workshop, CalRecycle staff edited this section so that program types are no longer compared directly to each other in

this revised Background Paper to avoid misleading comparisons. Also, this section includes updated information on cost effectiveness, illegal diversion, and more qualitative discussions to address individual strengths/weaknesses of each program type.

1. Nearly All Programs Returned Surveys

During April and May 2010, CalRecycle sent surveys to 67 program managers representing 297 known home-generated pharmaceutical collection programs.[†] This paper includes results based on the surveys returned to the department by June 10, 2010.

Many program managers represented more than one program and often more than one type of program. A one-page survey covered each of the three major program types (continuous collection programs, events, or mail-back programs, which are described below). As a result, a program manager may have filled out numerous surveys (one for each program) using the appropriate survey forms.

The survey forms listed at the SB966 Pharmaceutical Drug Waste Disposal Program Workshop web page (http://tinyurl.com/July2010PharmaWrkshop) varied by program type and included up to 25 questions that requested information on operations, funding, costs, collection amounts and security practices related to the standards in the Model Guidelines, over an eight-month period. Not all of the surveys were complete and some appeared to contain contradictory, unsupported, or unexplained responses. This is expected when dealing with complex topics and self-directed survey instruments.

Three main types of programs collect home-generated pharmaceuticals in California: continuous collection programs, events, or mail-back programs.

- **Continuous collection programs** are defined as drop-off locations that have scheduled collection hours at least weekly throughout the year.[‡]
- **Collection events** are defined as programs that provide:
    - Periodic drop-off opportunities at different locations, or
    - Infrequent drop-off opportunities at a single location, in comparison to continuous collection programs (e.g., an average of one or two days each month or less at the same location).
- **Mail-back collection programs** are defined as programs that transport drug waste through the USPS to an appropriate disposal location.[§]

[†] CalRecycle became aware of these programs through workshops, discussions and other communications. Additional programs may exist.

[‡] CalRecycle acknowledges that there is a spectrum of collection frequencies and approaches. The line between continuous collection programs and collection events is not black and white. For the purposes of this analysis, CalRecycle chose weekly collection as the threshold to distinguish between the two.

[§] Some pharmacies use tamper-resistant cardboard "mail-back" boxes (which hold 10 or 20 gallons). Pharmacies keep these containers on site until they are full. Individual consumers do not use these boxes, so this practice is included as part of the continuous collection programs operated at pharmacies.

Overall, CalRecycle identified 297 collection programs and program managers returned surveys for 256 programs (86 percent of total). The return rate varied by collection program as shown in Figure 2. The percentage of responses in each program type adequately represents current collection efforts in California.

Figure 2. Number of Programs and Number of Survey Responses by Program Type

	Number of Known Individual Programs	Total Number of Individual Programs Represented in Survey	Percentage of Programs with Survey Responses (%)
Continuous Collection			
- Pharmacies	112	102	**91%**
- Law Enforcement	65	63	**97%**
- Household Hazardous Waste Facilities	26	18	**69%**
- All Other	38	24	**63%**
Collection Events	53	46[**]	**87%**
Mail-back	3	3	**100%**
Total	**297**	**256**	**86%**

Based on the survey responses, the primary locations for continuous collection programs are pharmacies (102), law enforcement sites (63), and HHW collection sites (18). Ten other location types[††] contribute another 24 continuous collection sites, but the low numbers and differences between them make it difficult to draw conclusions regarding these locations.

The remainder of this paper focuses on the top three continuous collection location types (pharmacies, law enforcement, and HHW), as well as collection events and mail-back programs.

The responding collection events range from regular mobile collection events to limited hours at permanent household hazardous waste sites (e.g., first Saturday of each month) to highly coordinated events at multiple sites in a one-week period. Typical collection events are located in parking lots, vacant lots, pharmacies, senior centers, police substations, and HHW facilities.

[**] Program managers returned surveys for 50 of the known collection events. However, four surveys contained information from prior to 2009. CalRecycle became aware of two other programs after this analysis was completed. Finally, the "No Drugs Down the Drain" campaign consisted of more than 200 local one-day and ongoing pharmaceutical collection options during the week of Oct. 4-11, 2008. This campaign was not included because it predated the survey period. As a result, this paper reflects 46 survey respondents.

[††] Other locations include: clinics (6), hospitals (4), city halls (3), senior centers (3), dentists (2), door-to-door pickup (2), water districts (1), wastewater treatment plants (1), offices (1), and fire stations (1).

The three mail-back programs all began in the Bay Area in 2009: the City of San Francisco, Teleosis (a nonprofit organization in the Bay Area), and Santa Cruz County. While only a few mail-back programs currently operate in California, other states utilize mail-back collection programs (as discussed in Section IV. Overview of Programs Outside of California).

The number of surveys used in different analyses within this paper may vary because not all surveys included all the necessary information to complete the calculations or determinations for each question or topic.

The analyses in the remainder of this paper are based only on the survey responses, which do not include all programs in the "known universe," because the survey responses are considered "confirmed" programs and have data associated with them.

2. Approximately One-Third of Programs Meet the Voluntary Model Guidelines And So Are "Model" Programs

Note: In response to comments on the Background Paper for the July 2010 stakeholder workshop, CalRecycle staff edited this section so that this revised Background Paper now shows the percentage of programs that started before the voluntary model guidelines were approved.

The Model Guidelines emphasize the secure management of home-generated pharmaceutical wastes. To be a model program, a program must meet each of the criteria in the guidelines. The Model Guidelines are not mandatory or regulatory, so program managers can choose whether or not to follow them. While the Model Guidelines were designed to improve the consistency and quality of collection programs in California, programs that do not meet these voluntary Model Guidelines can still produce good results. However, for the purposes of this paper, a program that does not adequately meet all the criteria in the Model Guidelines is not considered a "model program."

Based on responses on the 256 programs surveyed, CalRecycle determined that 89 (35 percent) met all the standards in the voluntary Model Guidelines and were therefore model programs while 167 did not meet at least one criterion. Some criteria in the Model Guidelines, certain survey questions, and several survey responses contained ambiguity, so CalRecycle's model program determinations contain some subjective considerations. As shown in Figures 3 and 4, there are more model programs and higher percentages of model programs in some collection program types than other program types.

Figure 3. Numbers of Model and Non-Model Programs by Type

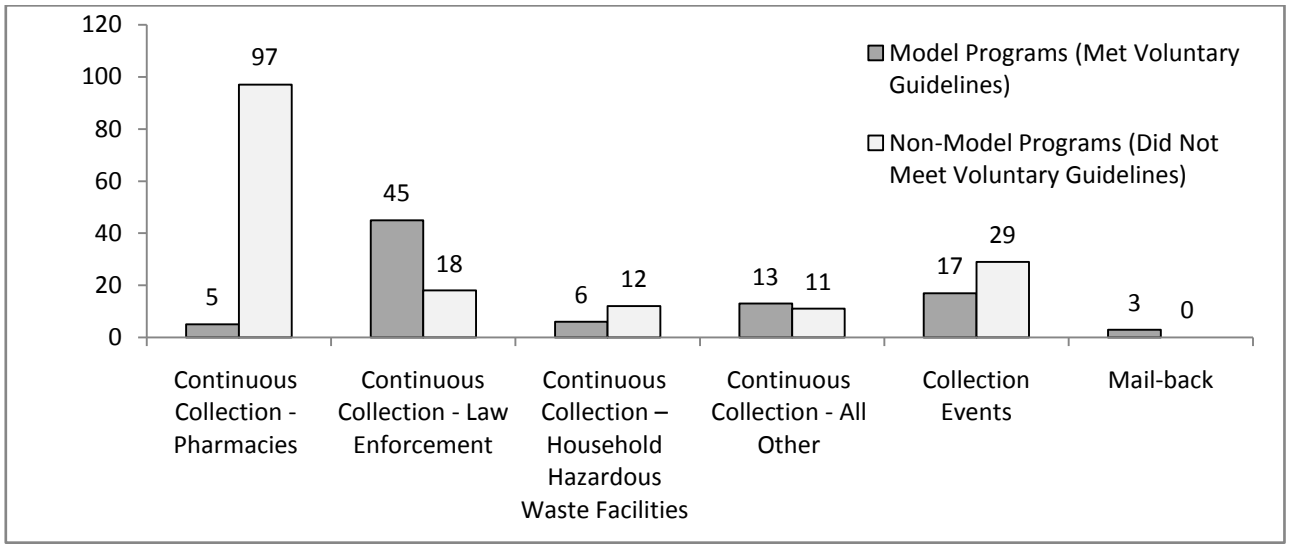


Figure 4. Numbers and Percentages of Model Programs

	Number of Model Programs (Met Voluntary Model Guidelines)	Number of Non-Model Programs (Did Not Meet Voluntary Model Guidelines)	Percentage of Model Programs Within Program Type
Continuous Collection			
- Pharmacies	5	97	5%
- Law Enforcement	45	18	71%
- Household Hazardous Waste Facilities	6	12	33%
- All Other	13	11	54%
Collection Events	17	29	37%
Mail-back	3	0	100%
Total	**89**	**167**	**35%**

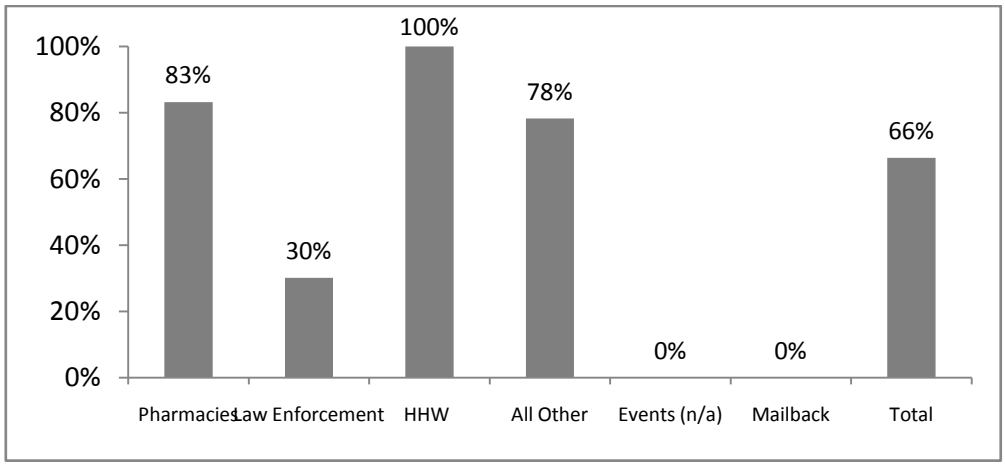
Of the 207 continuous collection programs, 69 adequately met the voluntary Model Guidelines and are model programs. Specifically, five pharmacy collection programs are models (5 percent), 45 law enforcement collection programs are models (71 percent), and 6 HHW collection programs are models (33 percent). Of the 46 collection events, 17 adequately met the voluntary Model Guidelines and are model programs (37 percent). Of the three mail-back collection programs, three adequately met the voluntary Model Guidelines and are model programs (100 percent). In general, mail-back and law enforcement programs most frequently met the Model Guidelines while pharmacies least frequently met them, but these conclusions need to be placed in context as discussed further below.

Some programs that existed prior to the adoption of the voluntary Model Guidelines have features that conflict with the guidelines. Figure 5 shows that most programs (136 out of 205 with data) were already operating at that time the voluntary Model Guidelines were approved in November 2008. Program managers had already invested significant time and/or resources to develop these existing programs, and changing them to meet the voluntary Model Guidelines prior to the survey period (approximately 18 months later) proved to be challenging for some. Changes that required additional infrastructure, resources or major changes to business procedures likely contributed to many programs not qualifying as model programs. As shown in Figures 5 and 6, nearly all of the pharmacy programs (83 percent) and all of the HHW (100 percent) were in place before the Model Guidelines were approved, which may help explain the lower rates of model programs in those two program types.

Figure 5. Number and Percentage of Programs Started Before Voluntary Model Guidelines Approved

	Programs that Predate Model Guidelines	Programs with known start dates	Percentage of Programs that Predate Model Guidelines‡‡
Continuous Collection			
- Pharmacies	84	101	83%
- Law Enforcement	19	63	30%
- HHW	15	15	100%
- All Other	18	23	78%
Events	n/a	n/a	n/a
Mailback	0	3	0%
Total	136	205	66%

Figure 6. Percentage of Programs Started Before Voluntary Model Guidelines Approved



‡‡ The percent of start dates reported out of the total survey responses were: pharmacies (99 percent), law enforcement (100 percent), HHW (88 percent), all other (96 percent), and mailback (100 percent) or 98 percent for all program types.

3. Different Programs Excel in Different Evaluation Areas: Safety, Accessibility, Cost-Effectiveness and Efficacy

This section evaluates five program types (Pharmacies, Law Enforcement, HHW, Collection Events, and Mail-Back) using the four factors specified in SB 966: safety, accessibility, cost-effectiveness, and efficacy. While SB 966 only calls for an evaluation of "model programs," for completeness this paper analyzes all programs that responded to the surveys.

This section first presents the following two introductory subsections:

- **Definitions and Limitations.** CalRecycle presents definitions of the four evaluation factors for the purposes of this paper, along with the major limitations associated with the analysis of each factor.
- **Program Evaluation Criteria Groupings.** CalRecycle groups the breaking points for each evaluation criterion into high, medium, and low categories.

CalRecycle then summarizes the results of the analysis and highlights the strengths and weaknesses of each of the following program types:

- **Pharmacy Program Evaluation**
- **Law Enforcement Program Evaluation**
- **HHW Program Evaluation**
- **Collection Event Program Evaluation**
- **Mail-Back Program Evaluation**

DEFINITIONS AND LIMITATIONS

Based on comments from numerous stakeholders, it is apparent that each of the following evaluation factors could be defined differently with different metrics. CalRecycle acknowledges this and, for the purposes of this paper, uses the definitions provided below.

CalRecycle also acknowledges that there are analytical limitations associated with each evaluation factor. While the response rate was high, the non-respondents may have been able to provide critical data different from those program managers that responded. As with any survey, different program managers may have interpreted the questions differently. Additionally, ambiguity in some of the survey questions may have caused confusion or resulted in incorrect responses. Incomplete surveys caused voids in the analysis, regardless of what the answer might have been had the response been provided. None of these analytical limitations renders the analysis fatally flawed, but did result in a more subjective and qualitative analysis.

CalRecycle also cautions readers about trying to compare the different program types. First, the data varied significantly within each program type as well as between program types; when this type of variability exists, one must use caution when comparing averages. Second, the program types vary

tremendously in whom they serve and how they provide their services. By way of example, grocery stores, fast food chains and high-end restaurants all provide food but do so very differently and each type excels in different situations. Similarly, the fundamental differences in service delivery models in different pharmaceutical collection program types make comparisons fruitless.

SAFETY (SECURITY)

Safety pertains to the security of pharmaceutical waste collection to prevent illegal diversion. The voluntary Model Guidelines contain many criteria designed to prevent or deter the public and/or program employees from taking pharmaceuticals out of the collection system for abuse or sale. CalRecycle attempted to capture these criteria in the survey questions. "Safer" collection programs meet more of the criteria and the "safest" qualify as model programs. One unmet criterion disqualifies a program from being considered a model. Also note that it may be possible to develop alternatives to the existing safety criteria in the Model Guidelines if collection system improvements can be identified in the future (e.g., more advanced practices become feasible such as shredding drug waste within each collection bin, automatically counting/tracking each pill, or tracking each pill bottle by automatically scanning barcodes or using RFID [Radio-frequency identification] tags).

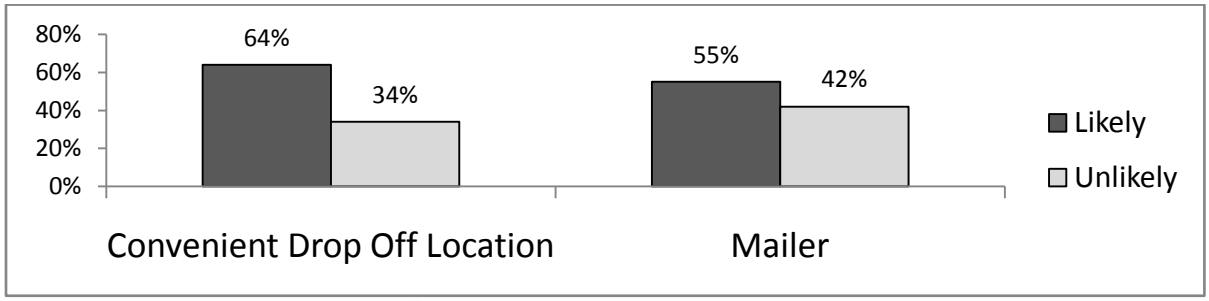
STATEWIDE ACCESSIBILITY (ACCESSIBILITY)

Public accessibility pertains to the ability of the public to utilize a collection program. Two factors that correlate to accessibility are the overall number of collection sites and their access hours. A tally of the returned surveys provides the number of sites for each program type, while the survey included questions regarding hours of operation per week.

It is important to realize that an increase in the number of collection sites in the state may not correlate to a more even geographic distribution throughout the state. Some people may not consider all types of sites equally accessible (e.g., anecdotal reports suggest some people are afraid of going to law enforcement sites), so the raw number may be misleading. Additionally, events may not be the most numerous programs, but in rural areas targeted local collection events could provide the easiest access compared to longer travel distances to continuous collection programs.

Accessibility is a very subjective measure. If tailored correctly to a target population, any or all of the program types could result in reasonable access for the public. Because accessibility is dependent on consumer behavior, consumer preferences will drive the actual use of collection programs. Based on a recent study of nearly 800 consumers in Washington and Oregon, 64 percent of those surveyed would be somewhat or very likely to take their home-generated pharmaceutical waste to a "convenient" drop-off location, while 55 percent of those surveyed would be somewhat or very likely to use a mail-back program for their home-generated pharmaceutical waste (see Figure 7 below).[6]

Figure 7. Washington/Oregon Residents' Medication Disposal Preferences



Hours of operation varied significantly within program type as well as between program types; readers should use caution when using or comparing averages when this type of variability exists. For example, among continuous collection programs, hours of operation may be a meaningful comparison. However, comparing these programs to mail-back programs is difficult, e.g., should the measure of accessibility for mail-back be picking up the envelope (limited hours) or putting it in the mail (unlimited hours)? In addition, the total number of hours may be less important than the "effective hours" in which people are likely to use a program, e.g., 24-hour access may not result in three times the effective access or triple the collection amounts compared to access during the "right" eight hours per day. Finally, because of their infrequent nature, collection events are not comparable regarding hours of operation but if tailored correctly to the population served could nonetheless be accessible.

COST-EFFECTIVENESS

Cost-effectiveness pertains to the amount of pharmaceuticals collected in comparison to the cost of the program used to collect them. CalRecycle's survey included questions about quantities collected and costs incurred. For this analysis, this metric is the average cost per pound for each program type.

Responses that did not include both costs and pounds of pharmaceutical waste collected were not included in the cost-effectiveness analysis. Errors or misreporting in overall cost or amount collected will impact the reliability of the cost-per-pound calculation.

Program costs may include: 1) advertising costs; 2) a medical or hazardous waste hauler's collection, transportation, disposal, and processing fees (hauler fees); and 3) administrative/staff time. Survey respondents could choose to provide costs for any or all of these categories. This analysis uses the cost data that program managers provided. For instance, many programs did not provide advertising costs because their program was mature enough that advertising was not needed, or funds were so limited that it was not an option. In addition, in many cases, staff time was not tracked and was not provided. Out of all survey responses, 51 percent of the programs and sites representing a cross section of all program types did not have associated staff costs. Because all costs were not included, the results presented here may be a low estimate. The cost data varied significantly within program type as well as between program types; when this type of variability exists, readers need to use caution when comparing averages.

CalRecycle did not adjust the reported amount of pharmaceutical waste collected to compensate for packaging discarded with the pharmaceuticals. While some programs encourage participants to remove packaging more than other programs, CalRecycle could not quantify the effect of this encouragement due to lack of accurate data. As a result, the cost effectiveness and efficacy relate to the combined weight of pharmaceuticals and associated packaging.

Most HHW programs do not track pharmaceutical weights separately from other household wastes they collect; most reported estimated weights. CalRecycle excluded one HHW program from the analysis because it reported a combined weight of household wastes and pharmaceuticals.

EFFICACY (COLLECTION RATE)

Efficacy is measured in three ways:

- The total amount of pharmaceutical waste collected by a program, divided by the number of operating days (pounds per operating day);
- The total amount collected by program type in California (total pounds per program type); and
- The average amount collected by each program type (average pounds per program).

A common criterion is pounds collected per capita; however, this metric does not work for this analysis because the population served by a collection program (e.g., one pharmacy) is unknown. As discussed above, both cost-effectiveness and collection rate rely on weight data for collected pharmaceuticals. CalRecycle did not adjust the reported amount of pharmaceutical waste collected to compensate for packaging discarded with pharmaceuticals. As a result, efficacy relates to the combined weight of pharmaceuticals and associated packaging.

For continuous collection programs, amount collected per day of operation equates to the amount collected at an individual site divided by the entire eight-month reporting period. For mail-back programs, the amount collected per day of operation equates to the amount collected from all mailers per program divided by the entire eight-month reporting period. For a one-day collection event, the amount collected is divided by one day to yield the pounds collected per day of operation. As a result, comparisons between continuous collection program types may be feasible. However, comparing these programs to collection events can be problematic because the boundaries of the program are less clear (e.g., a continuous collection program, a single envelope, a single event, all continuous collection programs, all envelopes, or the entire series of events).

PROGRAM EVALUATION CRITERIA GROUPINGS

Note: In response to comments on the Background Paper for the July 2010 stakeholder workshop, CalRecycle staff edited this section in the revised Background Paper so that:

- *Program discussion includes incidences of illegal diversion, as applicable.*
- *There is now an evaluation criterion for "accessibility" that covers: total number of possible drop-off locations per program type (e.g., total mailboxes and post offices in California).*
- *Pounds collected covers information reported in the surveys. The earlier version of this background paper included an estimate of pounds collected minus what could be attributed to packaging. However, based on input from stakeholders about discrepancies between packaging estimates (e.g., volume vs. pounds), this information now does not have an estimate with packaging removed.*

Each program type can be effective in different situations and with different target populations. CalRecycle evaluated each program type based on the four criteria (safety, accessibility, cost effectiveness and efficacy) to determine current practices and results. This paper represents a snapshot of pharmaceutical collection programs -- that is, as they were in late 2009 and early 2010. As programs continue to develop, they will evolve and may expand to fill new niches. Given the dynamic nature of this policy area, changes in statutes, regulations, and/or policy may dramatically change the way in which these services are delivered.

This section contains a factor-by-factor review of the information gathered during the survey, followed by a qualitative summary of each program type. As part of the qualitative summary, CalRecycle prepared a chart for each program type that visually illustrates the overall/average performance within each evaluation area (see Figure 8 for a blank sample). As noted above, it is difficult at best to compare results **across** programs, and CalRecycle has not done so in this analysis.

Figure 8. Relative Strengths of _____ Collection Programs

	Safety			Access			Cost	Efficacy		
	Number Models	Criteria Match	% Models	Current Sites	Hours/ Day	Possible Sites	Dollars/ Pound	Pounds/ Day	Current Pounds	Pounds/ Program
Strongest										
Medium										
Weakest										

CalRecycle has highlighted the appropriate box for each criterion examined in each program type to show relative strengths and weaknesses. When possible, CalRecycle used natural break points in the data for separating the program types into the "strongest," "medium" and "weakest" categories; however, the groupings are by nature somewhat subjective; selecting different break points would show different summary results. Figure 9 below shows the break points used to evaluate each program type. Those break points are described further below.

Figure 9. Evaluation Criteria Break Points

	Safety			Access			Cost	Efficacy		
	Number Models	Criteria Match	% Models	Current Sites	Hours/ Day	Possible Sites	Dollars/ Pound	Pounds/ Day	Current Pounds	Pounds/ Program
Strongest	>30	0-2	>70%	>70	>10	>1,000	<$3	>10	>10,000	>1,500
Medium	10-30	3-5	30%-70%	30-70	5-10	500-1,000	$3-$7	5-10	1,000-10,000	150-1,500
Weakest	<10	>5	<30%	<30	<5	<500	>$7	<5	<1,000	<150

- Safety:
  - "Number Models" = total number of existing programs in California that are model programs (meet voluntary Model Guidelines).
    - Strongest: more than 30 programs
    - Medium: 10 to 30 programs
    - Weakest: fewer than 10 programs
  - "Criteria Match" = how well existing programs were able to meet the individual criteria in the voluntary Model Guidelines.
    - Strongest: 0 to 2 guideline criteria not met by program
    - Medium: 3 to 5 guideline criteria not met by program
    - Weakest: more than 5 guideline criteria not met by program
  - "% Models" = percentage of existing programs in California that are model programs (meet voluntary Model Guidelines).
    - Strongest: more than 70 percent of programs
    - Medium: 30 percent to 70 percent of programs
    - Weakest: fewer than 30 percent of programs

- Accessibility:
  - "Current sites" = total number of existing programs in California.
    - Strongest: more than 70 programs
    - Medium: 30 to 70 programs
    - Weakest: fewer than 30 programs
  - "Hours/Day" = the average number of hours programs are available per day.
    - Strongest: more than 10 hours per day
    - Medium: 5 to 10 hours per day
    - Weakest: fewer than 5 hours per day
  - "Possible Sites" = total number of potential sites in California.
    - Strongest: more than 1,000 potential sites
    - Medium: 500 to 1,000 potential sites
    - Weakest: fewer than 500 potential sites
- Cost Effectiveness:
  - "Dollars/Pound" = the average dollars spent per pound of pharmaceuticals collected.
    - Strongest: less than $3.00 per pound
    - Medium: $3.00 to $7.00 per pound
    - Weakest: more than $7.00 per pound
- Efficacy:
  - "Pounds/Day" = the average number of pounds collected per day of operation.
    - Strongest: more than 10 pounds per day
    - Medium: 5 to 10 pounds per day
    - Weakest: less than 5 pounds per day
  - "Current pounds" = total amount collected by all existing programs in California.
    - Strongest: more than 10,000 pounds
    - Medium: 1,000 to 10,000 pounds
    - Weakest: less than 1,000 pounds
  - "Pounds/Program" = the average pounds collected by each program type.
    - Strongest: more than 1,500 pounds
    - Medium: 150 to 1,500 pounds
    - Weakest: less than 150 pounds

PHARMACY PROGRAM EVALUATION

SAFETY (SECURITY)

Program Safety (Security)

While 60 percent of the 102 responding pharmacy programs indicated that they were consistent with the Model Guidelines, CalRecycle determined that only 5 percent (5 programs) actually qualified as model programs. Pharmacy programs had issues with nine safety-related criteria; however, several of the criteria overlap and may artificially inflate this count. Three issues related to collection bin access and handling caused most disqualifications: two-key[§§] bins (93 percent), locking full bins (84 percent), and public access to bins (65 percent)[***].

As discussed above, most pharmacy programs predated the voluntary Model Guidelines so they may have more trouble converting over to the new criteria. Additionally, some pharmacies may not have been aware of the voluntary Model Guidelines or all the specific provisions until the Board of Pharmacy officially notified them in a newsletter just before the survey period (approximately March 2010).

Illegal Diversion Incidences

Any program's safety or security standards should be considered in the context of existing diversion incidences. Out of 256 collection sites or programs (including 102 pharmacies) representing 86 percent of all known programs operating in California any time in the last 15 years, no survey respondents reported any signs of illegal drug diversion. Washington state's "PH:ARM Pilot" program (using a less costly two-key collection process in pharmacies than California's Model Guidelines†††) also reported no diversion incidences in the 3½ years that 39 pharmacies in their original program have been operating collection programs.[7]

However, outside of these programs, one Northern California pharmacy stopped its collection program after a young woman's drug overdose death was suspected to be linked to drug diversion from the pharmacy's collection program.[8] Also, a Lynnwood, Wash., "pharmacist of the year" collected expired and

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[§§] California's Model Guidelines require that, "Bins located at pharmacies shall have a two-key security system--one in the possession of the collection site's designated responsible person and the other in the possession of the licensed hauler who will pick up the contents for appropriate destruction."

[***] The guideline requirements were designed to prevent pharmacy employees from individually accessing collected pharmaceutical waste and "public access to bins" indicates the pharmacy employees must handle collected pharmaceutical waste if the public does not have access to the collection bins.

[†††] The PH:ARM Pilot report [Grasso, Cheri, et al., (2009) Secure Medicine Return in Washington State, The PH:ARM Pilot. www.medicinereturn.com/resources] describes a two-key system following a less costly process: "Full boxes are removed from the container by two pharmacy staff using separate keys. After the box is taped shut, a tamper-evident seal is placed across the seams and a fax is sent to the central pharmacy warehouse notifying staff that a box of medicines will be arriving. Sealed boxes are shipped back to Bartell's central pharmacy warehouse, on the regular pharmacy route trucks. The unique numbers assigned to the boxes allow the custody and transportation to be tracked on a shipping notification form. At the central pharmacy warehouse, boxes are stored in a caged section of the warehouse until enough boxes accumulate for transportation to the disposal facility."

unexpired drugs from doctors, hospices, clinics, and pharmacy customers to allegedly distribute to less developed countries. Instead, he filled his pharmacy's regular supply pill bottles.[9] However, this may not be considered a true "collection program" since the drug store employing the pharmacist may not have known he was collecting home-generated pharmaceutical waste from customers.[10] No other home-generated pharmaceutical waste collection program in the world is known to CalRecycle to have illegally diverted its collected pharmaceutical waste.

STATEWIDE ACCESSIBILITY (ACCESSIBILITY)

Pharmacy program access hours ranged from five to 12 hours per day (average of nine hours per day). With approximately 6,100 pharmacies throughout California,[11] there are a very large number of possible locations for future pharmacy programs. As was shown previously in Figure 7, "Washington/Oregon Residents' Medication Disposal Preferences," 64 percent of nearly 800 consumers in Washington and Oregon would be somewhat or very likely to take their home-generated pharmaceutical waste to a "convenient" drop-off location. Nine out of 10 calls that the City of San Francisco's Toxics Reduction program receives regarding home-generated pharmaceutical waste disposal are from customers wanting to drop off their waste at pharmacies.[12] Anecdotally, people seem to prefer the point of sale such as a pharmacy as a convenient drop-off location as opposed to household hazardous waste facilities or law enforcement stations.‡‡‡

COST-EFFECTIVENESS

Statewide, 75 pharmacies provided sufficient cost information to calculate the costs per pound collected. Pharmacy program costs ranged from $1.00 to $16.67 per pound (average of $5.60 per pound). However, as noted above, almost all of these were not considered "model" programs. If pharmacy programs change their practices to meet the voluntary Model Guidelines, the costs could increase significantly. For example, based on written stakeholder comments after a July 20, 2010, workshop, if three specific pharmacy programs (representing 17 pharmacies) switched to the two-key system it would increase the annual costs by 141 percent (from $30,700 to an estimated $73,900, with an additional one-time cost of $15,360 for bin purchases).[13]

EFFICACY (COLLECTION RATE)

Statewide, 75 pharmacy programs provided sufficient information to calculate the pounds of pharmaceuticals collected. Pharmacy programs collected a total of 18,120 pounds during the survey period, corresponding to an average of 242 pounds collected per program. Pharmacy programs collected from 0.3 to 12.3 pounds per day of operation (average of 2.0 pounds per day).

QUALITATIVE SUMMARY

As presented in Figure 10, pharmacy programs:

- Excel in **accessibility** because of the large number of pharmacies in California;

‡‡‡ For instance, Melody LaBella with the Central Contra Costa Sanitary District and Karin North with the City of Palo Alto and current chair of the Bay Area Pollution Prevention Group have worked on home-generated pharmaceutical waste disposal issues for more than nine years each, including working with a variety of collection program types. In an Aug. 12, 2010 meeting with CalRecycle staff, each stated that people prefer point-of-sale disposal options.

- Have moderate **cost-effectiveness;**
- Have variable **efficacy** depending on the metric used; and
- Lag in **safety** because of the number of voluntary Model Guidelines criteria not met by the pharmacies.

Figure 10. Relative Strengths of Parmacy Collection Programs

	Safety			**Access**			**Cost**	**Efficacy**		
	Number Models	Criteria Match	% Models	Current Sites	Hours/ Day	Possible Sites	Dollars/ Pound	Pounds/ Day	Current Pounds	Pounds/ Program
Strongest										
Medium										
Weakest										

1. The biggest strengths of pharmacy programs:
    a. They are the point-of-sale for pharmaceuticals, so residents are familiar and comfortable with these locations.
    b. Pharmacies are designed for public access with thousands of convenient locations throughout California, sufficient parking, and handicap-accessibility, so the expansion and convenience potentials are high.
    c. Compared to any other program type, pharmacies have the greatest incentive to attract customers with collection programs since customers are more likely to purchase other items while there.
    d. Professionals familiar with pharmaceuticals staff the programs, so the learning curve for new programs should not be as steep.
2. The biggest challenges for pharmacy programs:
    a. Each has its own unique business practices, so a one-size-fits-all model (such as the voluntary Model Guidelines) may be challenging to implement.
    b. People associate pharmacies with drugs, so meeting some level of safety standards is even more important to prevent illegal diversion.
    c. The public typically cannot distinguish a controlled substance from a non-controlled substance, so as long as pharmacies are not allowed to collect controlled substances without law enforcement present, this will continue to complicate pharmacy programs.
    d. Adapting to the voluntary Model Guidelines will be difficult and expensive (especially for pre-existing programs), so acceptance and adoption of the guidelines may not be common or universal.
    e. Collection programs may not be seen as profitable or "good for business," so pharmacies may not commit the necessary resources and/or may be reluctant to set pharmaceutical collection as a priority.
    f. The voluntary Model Guidelines include prescriptive security requirements for pharmacies to meet Board of Pharmacy concerns about illegal diversion. These security requirements include a costly two-key collection bin and other requirements that make it difficult for pharmacies to comply with the voluntary Model Guidelines.

LAW ENFORCEMENT PROGRAM EVALUATION

SAFETY (SECURITY)

Program Safety (Security)

While 100 percent of the 63 law enforcement programs surveyed responded that they were consistent with the Model Guidelines, CalRecycle determined that only 71 percent actually qualified as model programs. Law enforcement programs had issues with five safety-related criteria. Three issues caused most disqualifications: controlled substances (29 percent), storage times (22 percent) and hauler registration (29 percent).

Illegal Diversion Incidences

No known incidences of illegal drug diversion have occurred in any law enforcement programs. At least one diversion incident outside of a collection program was reported.[14]

STATEWIDE ACCESSIBILITY (ACCESSIBILITY)

Statewide, 63 existing law enforcement programs responded to the survey. Law enforcement program access hours ranged from 3 to 24 hours per day (average of 19 hours per day). Anecdotally, people may not be as familiar with the locations or accessibility of law enforcement stations and have expressed concerns about taking their pharmaceuticals to them. With approximately 900 law enforcement locations throughout California,[§§§] there are many possible sites for future law enforcement programs.

COST-EFFECTIVENESS

Statewide, each of the 63 law enforcement programs surveyed provided sufficient cost information to calculate the costs per pound collected. Law enforcement program costs ranged from $0.38 to $13.89 per pound (average of $4.56 per pound).

EFFICACY (COLLECTION RATE)

Statewide, 63 law enforcement programs provided sufficient information to calculate the pounds of pharmaceuticals collected. Law enforcement programs collected a total of 194,522 pounds during the survey period, corresponding to an average of 3,088 pounds collected per program. Law enforcement programs collected from 0.1 to 34.7 pounds per day of operation (average of 7.1 pounds per day).

Law enforcement programs often have a 24-hour presence and often locate drop boxes outdoors. Some law enforcement programs reported that small businesses deposit their pharmaceutical waste, which is not considered home-generated, in these drop boxes. This inflates the amounts, increases the program disposal costs, would contradict the disposal requirements for any business generating that waste,[****] and

[§§§] Based on CalRecycle staff estimates from samplings of number of stations referenced here: www.road-police.com/police/california/california_police.html.

[****] According to the California Medical Waste Management Act.

constitutes unfair competition for any business using this free disposal method intended only for resident use.[††††]

The largest law enforcement program reported that during its initial six-month startup period (which corresponded with the CalRecycle survey period), the program suspected a large amount of business waste disposal was occurring. Additionally, the amount of pharmaceuticals collected during the six-month startup period was much higher than subsequent periods. Residents may have disposed of a large amount of stockpiled pharmaceuticals. As a result, the representativeness of the data for that program may be questionable, which could have resulted in somewhat inflated collection rates compared to long-term collection rates.

QUALITATIVE SUMMARY

As presented in Figure 11, law enforcement programs:

- Excel in **safety** by having a large percentage of model programs;
- Have moderate **accessibility** and **cost-effectiveness**; and
- Excel in program **efficacy** (although this may be due in part to suspect data).

Figure 11. Relative Strengths of Law Enforcement Collection Programs

	Safety			**Access**			**Cost**	**Efficacy**		
	Number Models	Criteria Match	% Models	Current Sites	Hours/ Day	Possible Sites	Dollars/ Pound	Pounds/ Day	Current Pounds	Pounds/ Program
Strongest										
Medium										
Weakest										

1. The biggest strengths of law enforcement programs:
    a. They are secure locations, so residents should be safe and illegal diversion should be rare.
    b. There are nearly 1,000 locations currently in the state, so the expansion and convenience potentials are good.
    c. Most existing programs conformed well to the voluntary Model Guidelines, so additional programs should be able to conform, too.
    d. They can more easily meet the requirements for collecting controlled substances, so they could be convenient one-stop locations.
2. The biggest challenges for law enforcement programs:
    a. People either think of these locations as dangerous or are unaware of their whereabouts, so getting full public participation may be difficult.
    b. Many are facing severe budgetary and funding shortfalls, so they may not have the resources and/or may be reluctant to set pharmaceutical collection as a priority.

[††††] According to Section 17200 of the California Business and Profession Code.

HHW PROGRAM EVALUATION

SAFETY (SECURITY)

Program Safety (Security)

While 78 percent of the 18 HHW programs responded that they were consistent with the Model Guidelines, CalRecycle determined that only 33 percent actually qualified as model programs. As discussed above, all of the HHW programs predated the voluntary Model Guidelines so they may have more trouble converting over to the new requirements. HHW programs had issues with three safety-related criteria. Issues related to documentation (50 percent) and storage times (44 percent) caused most disqualifications.

Illegal Diversion Incidences

No known incidences of illegal drug diversion have occurred at any household waste facilities.

STATEWIDE ACCESSIBILITY (ACCESSIBILITY)

Statewide, 18 existing HHW programs responded to the survey. HHW program access hours ranged from one to nine hours per day (average of three hours per day). With approximately 140 HHW sites throughout California, there are some additional possible locations for future HHW collection programs.

COST-EFFECTIVENESS

Statewide, 15 HHW programs provided sufficient cost information to calculate the costs per pound collected. HHW program costs ranged from $0.13 to $6.38 per pound (average of $2.86 per pound). This average is considerably lower than the average costs of other programs; however, the weights of pharmaceuticals at HHW programs are more likely to be estimated rather than measured, which could impact the cost-effectiveness results (e.g., if the estimated amounts are twice the actual weight, the cost per pound will be half what it should be).

EFFICACY (COLLECTION RATE)

Statewide, 16 HHW programs provided sufficient information to calculate the pounds of pharmaceuticals collected. HHW programs collected a total of 9,349 pounds during the survey period, corresponding to an average of 584 pounds collected per program. HHW programs collected from 0.4 to 10.3 pounds per day of operation (average of 2.0 pounds per day).

QUALITATIVE SUMMARY

As presented in Figure 12, HHW programs:

- Excel in **cost-effectiveness** (although this may be due in part to suspect data);
- Have moderate **safety** and **efficacy;** and
- Lag in **accessibility** due to relatively few existing programs, few potential sites, and limited hours.

Figure 12. Relative Strengths of HHW Collection Programs

	Safety			Access			Cost	Efficacy		
	Number Models	Criteria Match	% Models	Current Sites	Hours/ Day	Possible Sites	Dollars/ Pound	Pounds/ Day	Current Pounds	Pounds/ Program
Strongest										
Medium										
Weakest										

1. The biggest strengths of HHW programs:
    a. They are existing programs that can handle a variety of toxic materials, so they can function as one-stop locations.
    b. Pharmaceuticals comingled with HHW represent a relatively small amount compared to all HHW and can be collected and disposed together with relative efficiency following existing practices.
2. The biggest challenges for HHW programs:
    a. There are fewer than 150 total HHW sites in the state, so convenience and the potential for expansion is low.
    b. Many people staff and visit HHW sites, so meeting safety standards is important to prevent illegal diversion.
    c. Many local governments that run HHW programs are facing severe budgetary and funding shortfalls, so they may not have the resources and/or be reluctant to set pharmaceutical collection as a priority.

COLLECTION EVENT EVALUATION

SAFETY (SECURITY)

Program Safety (Security)

While 76 percent of the 46 collection events responded that they were consistent with the Model Guidelines, CalRecycle determined that only 37 percent actually qualified as model programs. Collection events had issues with three safety-related criteria. Issues related to documentation (46 percent) caused most disqualifications.

Illegal Diversion Incidences

No known incidences of illegal drug diversion have occurred at any collection events.

STATEWIDE ACCESSIBILITY (ACCESSIBILITY)

Statewide, 46 existing collection events responded to the survey. Event access hours ranged from three to 12 hours per day (average of seven hours per day) when events were held. Events can be held at numerous types of locations, so there are numerous possible locations for future collection events.

COST-EFFECTIVENESS

Statewide, 36 collection events provided sufficient cost information to calculate the costs per pound collected. HHW program costs ranged from $0.87 to $16.67 per pound (average of $6.06 per pound). It appears that jurisdictions with limited resources are more likely to use collection events. If costs to open and/or operate a continuous collection program are prohibitive, a jurisdiction may operate collection events to reach all residents with some level of collection service. Collection events appear to be more common in areas with large dense populations such as the City of Los Angeles or the Bay Area, and in rural jurisdictions where they provide at least some level of service to a diffuse population.

EFFICACY (COLLECTION RATE)

Statewide, 36 collection events provided sufficient information to calculate the pounds of pharmaceuticals collected. Events collected a total of 5,040 pounds during the survey period, corresponding to an average of 140 pounds collected per program. Collection events collected from 2.5 to 482.0 pounds per day of operation (average of 163.1 pounds per day). Again, these large quantities represent the amounts collected on only the days that events occurred, rather than on a daily, continuous basis.

Although events appear effective in terms of pounds collected per day, the final report for the California "No Drugs Down The Drain! Statewide Campaign, October 4-11, 2008" concluded, "While they can be successful in educating residents, event-based disposal is not a long-term solution. Some residents are not able to attend events, and stockpiling medication until a future event is not an option for many who are concerned about accidental poisoning, misuse, abuse, or diversion."[15]

QUALITATIVE SUMMARY

As presented in Figure 13, collection events:

- Have moderate **safety**, **accessibility,** and **cost–effectiveness;** and
- Have variable **efficacy** depending on the metric used, which should be expected for an approach that may be best at addressing specific needs in certain situations.

Figure 13. Relative Strengths of Collection Events

	Safety			Access			Cost	Efficacy		
	Number Models	Criteria Match	% Models	Current Sites	Hours/ Day	Possible Sites	Dollars/ Pound	Pounds/ Day	Current Pounds	Pounds/ Program
Strongest										
Medium										
Weakest										

1. The biggest strengths of collection events:
    a. They are flexible and can happen in a variety of locations, so residents have reasonable access to some level of service.
    b. They can handle large volumes of materials in a short amount of time, so they may be more effective at dealing with existing stockpiles.

   c. Relative to other law enforcement duties, law enforcement officers may be more likely to staff a one-time event in order to collect controlled substances rather than run a full-time collection program.
   d. They can be effective by increasing public awareness and giving stakeholders initial experience with collection issues, which may make events a potentially effective first step toward starting a continuous collection program.
2. The biggest challenges for collection events:
   a. People may not hear about events, so without adequate publicity they may not reach the intended audiences or get full public participation.
   b. Staffing commitments for events can be onerous and costly for the amount of pharmaceutical waste collected.
   c. Many people staff and visit collection events, so meeting some level of safety standards may be difficult.
   d. Many local governments that run collection events are facing severe budgetary and funding shortfalls, so they may not have the resources and/or may be reluctant to set pharmaceutical collection as a priority.

MAIL-BACK PROGRAM EVALUATION

SAFETY (SECURITY)

Program Safety (Security)

All three mail-back programs responded that they were consistent with the Model Guidelines, and CalRecycle confirmed that they all qualified as model programs. Mail-back programs had no issues with safety-related criteria. In mail-back programs, only the generator (i.e., the resident) handles pharmaceuticals and then the USPS takes custody of the envelopes, so there are very few opportunities for security issues to arise.

Illegal Drug Diversion

The following mail-back-related example of potential illegal drug diversion was not part of any official collection program. However, it does indicate the security concerns surrounding such programs even though the USPS boasts a 94 percent conviction rate for crimes that range far afield from stolen mail or forged money orders.[16] The USPS investigated multiple reports of prescription medication mailed to veterans from the Veterans Administration that disappeared from a South Sacramento post office.[17]

STATEWIDE ACCESSIBILITY (ACCESSIBILITY)

Statewide, three existing mail-back programs responded to the survey. Mail-back access hours ranged from six to 10 hours per day (average of 8 hours per day) for mailer pickup. Mailboxes are always available, so drop-off access is essentially 24 hours per day. Pharmacies, government offices, or a variety of other locations could distribute mailers, so there are a very large number of possible distribution locations. Drop-off locations are even more plentiful with approximately 1,850 post offices and approximately 21,310 mailboxes in California.[18] Residents could even give mailers to their letter carriers. Especially for homebound residents and those in rural areas, mail-back programs allow the public to send packages at anytime at any mailbox. In terms of potential drop-off locations, mail-back programs potentially offer the greatest accessibility. Santa Cruz County's relatively small mail-back program has the highest reported return rate so far (68 percent returned/distributed), possibly because a pharmacy

distributed mailers specifically to people who, for various reasons, could not use a nearby pharmaceutical drop-off site.

COST EFFECTIVENESS

Statewide, all three mail-back programs provided sufficient cost information to calculate the costs per pound collected. Mail-back costs ranged from $4.59 to $8.10 per pound (average of $6.54 per pound). Because all mail-back programs started in 2009 and are relatively new in California, CalRecycle only includes the costs and pounds collected for returned mailers. Program managers pay for mailers up-front regardless of whether they are subsequently used or not. If generators (residents) do not return some mailers, then overall cost per pound will increase (e.g., if residents returned only half of the mailers, the cost per pound would double). A mailer's $3.65 flat rate cost per envelope may encompass more upfront costs than the reported costs from pharmacy programs (e.g., staff time, kiosk cost and maintenance, and lost retail space, etc.). Finally, if residents put more pharmaceuticals in each envelope, the cost-effectiveness increases (i.e., a lower cost per pound) because the current mail-back programs use flat rate shipping arrangements. However, encouraging residents to hold onto materials longer and send fewer, fuller envelopes may increase illegal diversion opportunities. In addition, Walgreens has made postage-paid mailers available in its stores nationwide for $2.99 each,[19] and at least 200 Kaiser Permanente Hospitals in California are offering the same mailers for $4.95 each.[20] Anecdotally, Kaiser has had considerable customer demand.

EFFICACY (COLLECTION RATE)

Statewide, all three mail-back programs provided sufficient information to calculate the pounds of pharmaceuticals collected. Mail-back programs collected a total of 898 pounds during the survey period, corresponding to an average of 299 pounds collected per program. Mail-back programs collected from 0.1 to 3.2 pounds per day of operation (average of 2.1 pounds per day).

QUALITATIVE SUMMARY

As presented in Figure 14, mail-back programs:

- Excel in **safety** by having 100 percent model programs;
- Have variable **accessibility** with low current accessibility but great potential accessibility;
- Have moderate **cost-effectiveness** (although this is dependent on high mailer return rates); and
- Lag in **efficacy** due to relatively few existing programs.

Figure 14. Relative Strengths of Mail-Back Collection Programs

	Safety			Access			Cost	Efficacy		
	Number Models	Criteria Match	% Models	Current Sites	Hours/ Day	Possible Sites	Dollars/ Pound	Pounds/ Day	Current Pounds	Pounds/ Program
Strongest										
Medium										
Weakest										

1. The biggest strengths of mail-back programs:
    a. They do not require any expertise, so mailers can be distributed in a variety of ways at almost any location.
    b. There are convenient USPS drop-off locations across California, so the potential for convenience and expansion is very high.
    c. The costs are all paid up-front, so there are no hidden or unexpected costs to contend with.
    d. No intermediary handles the pharmaceuticals (other than the USPS), so safety is not as much of a concern.
    e. Fewer regulations are necessary (e.g., CDPH's policy to regulate consolidated home-generated pharmaceutical waste) since no intermediary consolidates or is considered to generate the waste.
2. The biggest challenges for mail-back programs:
    a. There are only three programs in the state, so it may be seen by some as an unproven approach.
    b. The costs are all paid up-front, so a very high return rate is necessary for the method to be cost-effective.

III. Challenges and Barriers

CalRecycle worked closely with numerous agencies to develop the Model Guidelines[21] that were formally adopted by CalRecycle in November 2008, with a subsequent revision in February 2009. Agencies participating included the California Department of Public Health (CDPH), the Department of Toxic Substances Control (DTSC), the State Water Resources Control Board (SWRCB), and the California State Board of Pharmacy (CBOP), and as well as other stakeholders. The Model Guidelines contain criteria and procedures for model pharmaceutical waste collection programs by type of program. Programs are not required to follow the Model Guidelines but they must be consistent with them to be considered a "model program" under SB 966.

This section discusses the following five challenges and barriers common among California home-generated pharmaceutical collection programs:

1. High Cost of Safe Collection;
2. Lack of Public Awareness and Participation;
3. Lack of Sustainable Funding;
4. Lack of Goals; and
5. Complexity of Current Requirements, Policies and Authority.

Through survey information presented and discussed in Section IV, CalRecycle identified these challenges and barriers for current programs. The surveys focused on implementation of the Model Guidelines (see Appendix A: *Criteria and Procedures for Model Home-Generated Pharmaceutical Waste Collection and Disposal Programs*) and for this reason, the explanations below reference the Model Guidelines.

1. High Cost of Safe Collection

Certain requirements in the Model Guidelines present unique challenges to some collection programs. Safety (security) issues are usually the primary reason why existing programs do not qualify as model programs. Meeting the requirements often can add more costs as specific participants are required (law enforcement personnel and registered haulers), more bins and pickups are needed (two-key bins and secured containers), and special handling considerations are implemented (separate handling, weighing, and record keeping). Treating home-generated pharmaceutical waste as medical or hazardous waste either through transportation or disposal (e.g., incineration vs. hazardous waste landfills) can also be costly. A few of these issues are illustrated in this section.

COLLECTION OF CONTROLLED SUBSTANCES

Controlled substances represent approximately 10 percent of all prescriptions written in the United States. In the state of Maine's recent pilot mail-back program, controlled substances represented 17 percent of all drugs returned. Given that many take back programs cannot accept controlled substances, mail back may offer convenience and privacy with these sensitive drugs.

Under federal statute (the U.S. Controlled Substances Act), controlled substances cannot be collected unless a sworn law enforcement officer is onsite to take custody of, document, and dispose of these

medications to prevent illegal diversion and abuse. Based on information available to CalRecycle, the United States is the only country that has these requirements (see Section IV, *1. International Guidelines and Programs*).

Making it easier for non-law enforcement programs to collect controlled substances, and making it easier to dispose of all home-generated pharmaceutical waste within California, would decrease costs and make program implementation easier and more attractive. This may occur when regulations are promulgated as part of the recently passed S. 3397 (also see Section IV, *2. National Programs*, Federal Legislation and Regulations).

HAULING CONSOLIDATED WASTE

If home-generated pharmaceutical waste is consolidated, CDPH considers it medical waste, which must be transported by a registered medical waste hauler. Transporting collected home-generated pharmaceutical waste using only haulers registered with CDPH may be more expensive than other options. At least nine pharmacies in the state used the larger cardboard "mail-back" boxes but this method does not use a registered waste hauler.

INCINERATION USED MORE THAN LANDFILLS

Disposal requirements and disposal options vary depending on how the materials are collected, consolidated, mixed with other materials, and on who does the collecting. The costs of these options are very different and impact the costs of collection programs.

BUSINESSES

Businesses tend to prefer the least expensive disposal option, which could be at in-state landfills. However, shipping home-generated pharmaceutical waste with existing larger volumes of medical or hazardous waste that are sent out of state for incineration may be more efficient than in-state landfill disposal. For instance, a relatively small amount of home-generated pharmaceutical waste could be sent in a small truck to an in-state hazardous waste landfill. However, that truck would be taken out of circulation from local hauling collection routes. In contrast, larger volumes of medical or hazardous waste are already sent out of state for incineration so combining all of these wastes may be less expensive overall.[22] Shipping pharmaceutical waste to landfills in California may also be more expensive depending upon the infrastructure of the company collecting the waste. Some companies haul waste and operate incinerators out of state and may find that their overall internal costs are lower to ship to their incinerator than to use an in-state landfill.[23]

LAW ENFORCEMENT

If controlled substances are collected, they must be incinerated (i.e., "destruction") according to federal law.[‡‡‡‡] California law enforcement agencies that collect controlled and/or non-controlled substances generally use two in-state waste-to-energy incinerators, which are permitted to accept this waste, but not medical waste, hazardous waste, or liquids.[24] Commercial medical or hazardous waste haulers that cannot use these in-state waste-to-energy incinerators for their medical or hazardous waste, also collect non-

[‡‡‡‡] Controlled Substances Act, Section 881 (f)(2) and Code of Federal Regulations, Section 1307.21 (b)(3)

controlled substances at some law enforcement sites and send it out of state for incineration because of the lower internal costs.

HHWs

Generally, HHW collection programs comingle home-generated pharmaceutical waste with other household hazardous wastes such as pesticides. The standard practice is for local governments to send out a Request for Proposals, select a commercial hauler with the winning bid, and the hauler usually chooses the disposal facility location. Because there are no known commercially-available medical waste or hazardous waste incinerators in California, the hazardous waste hauler generally ships it out of state for incineration.[25,26]

As described above, businesses, law enforcement and HHW programs may choose incineration more often because it allows controlled substances to be handled correctly and because the overall cost/benefits may be greater for incineration over in-state hazardous waste landfill disposal. In the future, if larger collection volumes could be managed at in-state disposal facilities, cost efficiencies could improve.

Two-Key Locking Collection Bins

To meet the Model Guidelines, bins located at pharmacies must have a two-key security system so that no individual may access the drug waste alone: the pharmacy's designated responsible person would have one key and the licensed hauler would have the other key. In addition, to save on waste hauling expenses, employees at many pharmacies with publicly accessible bins will empty the bin and store the bin contents behind the counter to avoid extra waste hauler trips. The two-key security system complicates pharmacies' attempts to minimize waste hauler trips and consolidate waste when bins are full. For example, Marin County, which began collection in 2004, would exceed its $14,000 annual budget if the county paid for a two-key collection bin for each of its 24 participating pharmacies. Also, based on written stakeholder comments after the July 20, 2010 workshop, if three specific pharmacy programs (representing 17 pharmacies) switched to the two-key system it would increase their annual costs by 141 percent (from $30,700 to an estimated $73,900, with an additional one-time cost of $15,360 for bin purchases).[27]

Use of Secure Containers at HHW Sites

The majority of HHW facilities comingle drug waste with other HHW—often in open 55-gallon drums to allow room for other waste to be deposited easily. Unfortunately, this also allows much easier access to deposited pharmaceuticals. To meet the Model Guidelines, an additional bin may be needed (at a cost of approximately $600 each) so materials are not comingled and remain secure. However, the relatively small amounts of pharmaceutical waste compared to other waste collected at HHW sites makes it somewhat impractical for pharmaceuticals to be managed separately from other HHW; it could lead to prolonged storage times and much higher disposal costs (costs rise exponentially for smaller containers).

Record Keeping and Data Collection

Weighing, logging and tracking drug waste before and after transport is meant to prevent illegal diversion, and can also be useful in performance measures. Most survey respondents for HHW facilities reported they comingled pharmaceutical waste with other HHW, which may make it more difficult to weigh, log and

track pharmaceuticals separately. As discussed above, if HHW sites must treat other waste and pharmaceuticals differently, their costs will be higher.

2. Lack of Public Awareness and Participation

A common challenge with any type of collection program is achieving high public awareness and participation rates. Local governments facing significant budget shortfalls fund most collection programs. Given that program costs increase with more collection, local governments are in one sense penalized as participation increases.

There is not enough data from programs outside of California to draw any conclusions about types of programs associated with high public participation, but anecdotally, public outreach and convenience play an important role.

3. Lack of Sustainable Funding

Local governments currently fund approximately 83 percent of all California collection programs. Of that percentage, most funding comes from counties, local waste and water agencies, and to a lesser extent, cities. Pharmacies provide funding for 15 percent of collection programs. The remainder comes from various other sources, such as nonprofit organizations and waste companies. Although SB 966 encourages a cooperative relationship with all stakeholders, CalRecycle is not aware of any funding from pharmaceutical manufacturers for collection programs in California. However, there is public support for pharmaceutical companies assuming this responsibility. According to a recent survey of consumers in Washington and Oregon, 64 percent of those who responded agreed (strongly or somewhat) that pharmaceutical companies should be responsible for creating a take-back program for safe disposal of unused medicines.

This contrasts significantly with other countries (See Section IV. Overview of Programs Outside of California), where private sector manufacturers and retailers play a significant role in funding and managing pharmaceutical collection programs, many through product stewardship programs. Product stewardship programs use a private-sector approach to managing discards.[28] Producers are generally able to implement programs either individually or by joining together with other producers through a product stewardship organization that collects, properly manages, and interacts with the state oversight agency on its behalf.

4. Lack of Goals

There are two basic reasons for implementing pharmaceutical collection programs that address improper disposal. The first is to reduce the amount of pharmaceuticals that enter the environment, particularly in surface and groundwater. The second reason is to reduce illegal diversion of pharmaceuticals and prevent drug abuse. Goals set for the collection of unwanted household pharmaceuticals must address both reasons.

SB 966 does not provide any performance goals to measure success. Performance goals similar to CalRecycle's goal of 50 percent waste diversion in California by the year 2000 could drive the creation of programs and help set realistic standards for pharmaceutical waste collection throughout the state. Goals accompanied with incentives (e.g., limiting long-term corporate liability[29]) can be particularly effective in driving program activity. To be effective, measures must take into account information about the amounts of pharmaceuticals sold/prescribed in California, the amounts unused, and the amounts that are eventually collected.

Additionally, a subset of measures could help track program effectiveness and guide program improvements. For example, some studies indicate that pharmaceuticals enter surface and groundwater largely due to human excretion. This suggests that collection programs may not make a large reduction on pharmaceuticals water emissions, even if programs collect all unwanted drugs. However, the studies are industry-sponsored and few in number, making it difficult to draw firm conclusions. Tracking pharmaceutical impacts on water quality could provide a deeper understanding of pollution sources and aid in finding effective solutions.

Even if goals are established, an entity must have the authority to gather necessary data from participants in order to measure progress toward meeting these goals. Otherwise, based on CalRecycle's experience with other collection streams and based on staff knowledge of pharmaceutical collection programs outside of California, there will not be data available to determine whether goals are met or if the program is successful.

Regardless, however, there is agreement that substance abuse is a growing concern among families and communities; and providing convenient collection, supported with public education, could help address this issue. In addition to establishing collection goals, programs could also establish convenience goals and track educational efforts to better ensure adequate public participation.

5. Complexity of Requirements, Policies and Authority

The Model Guidelines state, "Any participating entity must determine what permits or approvals are needed for home-generated pharmaceutical waste collection." However, the current patchwork of laws, regulations, and policies can be a challenge for any collection program. For example, Waste Management, Inc., reports that California's regulation of pharmaceutical waste is "extremely complex and these wastes may be regulated as a hazardous waste, a medical waste, or a solid waste under California law."[30] Entities may be discouraged from starting collection programs due to concerns and uncertainty about the applicable definitions, requirements and legal options for collecting, handling and disposing of home-generated pharmaceutical waste. Through statute, regulation, or policy, each of the following federal and state departments affects the collection and disposal of home-generated pharmaceutical waste to some degree (also see Section I, *4. Current status of regulations, statutes, and policy*).

- ## U.S. DRUG ENFORCEMENT ADMINISTRATION (DEA)

  There are no DEA regulations specific to home-generated drug collection, but under the U.S. Controlled Substances Act the DEA governs controlled substances (Title 21, Chapter 13, Drug Abuse Prevention and Control). These regulations oversee the manufacture and distribution of narcotics, stimulants, depressants, hallucinogens, anabolic steroids, and chemicals used in the illicit production of controlled substances and define who may possess controlled substances, which impacts disposal of a controlled substance. The Secure and Responsible Drug Disposal Act of 2010 (S 3397) (See Section IV. Overview of Programs Outside of California), amends the Controlled Substances Act to allow for the safe and effective collection and disposal of controlled substances. The specific changes will be forthcoming through a rulemaking process to start in late 2010, at the earliest.

- ## CALIFORNIA BOARD OF PHARMACY

  Pharmacies lack statutory provisions for pharmaceutical collection, unlike the recently granted provisions for sharps collection. California law currently does not authorize pharmacies to accept the return of home-generated pharmaceutical waste. SB 966 states programs consistent with the Model Guidelines are "…in compliance with state law and regulation…" but SB 966 did not amend the Business and Professions Code to specifically authorize pharmacies to accept home-generated pharmaceuticals, which creates some confusion about how to interpret the legalities of pharmacy participation. Regardless, the California Board of Pharmacy's February 2010 newsletter stated, "The Board expects all pharmacies to use the [CalRecycle] Guidelines for any 'Take Back' program they offer the public."[31]

  Likewise, California law did not authorize pharmacies to accept the return of sharps from the public until Senate Bill 821 (Committee on Business, Professions and Economic Development, Chapter 307, Statutes of 2009) added appropriate language to the Business and Professions Code in October 2009. Until that time, the California Board of Pharmacy had a stated policy that it did not anticipate intervening in sharps collection programs unless necessitated by a complaint or public safety issue. A similar provision in California law would clarify the requirements for home-generated pharmaceutical waste.

- ## DEPARTMENT OF TOXIC SUBSTANCES CONTROL (DTSC)

  DTSC regulates hazardous waste including approximately 5 percent of all pharmaceutical waste[32] (e.g., nitroglycerin, warfarin, and some chemotherapy agents dispensed from hospitals), but does not regulate home-generated pharmaceutical waste. DTSC's website states, "Pharmaceutical waste produced by a household is exempt from classification as hazardous waste or medical waste. This means that a household may legally dispose of their waste pharmaceuticals and personal care products in the solid waste stream or into the sanitary sewer ('down the drain'). While these practices are legal, they may not be the environmentally preferred ways for a household to dispose of unwanted pharmaceuticals."[33]

- ## CALIFORNIA DEPARTMENT OF PUBLIC HEALTH (CDPH)

  The Medical Waste Management Program of the CDPH does not have statutory authority to regulate home-generated pharmaceutical waste. Instead, CDPH applies a best waste management policy consistent with current, existing waste collection models for home-generated pharmaceutical waste. This current policy monitors home-generated pharmaceutical waste at registered consolidation points to ensure proper containment, storage, and treatment. CDPH's policy is similar to its current regulation of home-generated sharps waste, which it defines as medical waste, when the sharps are collected at a consolidation point.

As noted, there is an absence in current statute of a specific definition of home-generated pharmaceutical waste and which agency has authority regardless of how it is collected, consolidated, managed and disposed. Instead, various federal and state departments (DEA, Board of Pharmacy, DTSC, CDPH) exercise statutory authority, regulatory authority or have current policies over home-generated pharmaceutical collection, management, and disposal with different levels of consistency and clarity. In turn, the separate statutes, regulations and policies can make it challenging for local jurisdictions to

develop and maintain effective collection and disposal programs that they know conform to legal requirements. Clear statutory definition of which department or agency has sole authority over defining home-generated pharmaceutical waste and determining issues related to collection, consolidation, management, and disposal is essential to providing for a successful program that safely manages collection and disposal of home-generated pharmaceutical waste.

IV. Overview of Programs Outside of California

Note: In response to comments on the Background Paper for the July 2010 stakeholder workshop, CalRecycle staff edited this section so that there is more information on programs outside of California in the revised Background Paper.

Other countries and states face similar challenges with managing unwanted pharmaceuticals. CalRecycle found examples of pharmaceutical collection programs in a number of other countries and states and analyzed them for their approach, costs, and effectiveness, where information was available.

Below are several programs that stand out for reasons noted. Much of the information on programs outside of the United States comes from the Health Canada report, *Pharmaceutical Disposal Programs for the Public: A Canadian Perspective*,[34] which serves as a reference for readers seeking more detailed information.

Basic information about many of these international and state programs is captured in the table in Appendix B: *Overview of Pharmaceutical Collection Programs Outside of California*.[35] While the descriptions below include cost information as it is reported, cost comparisons should not be used to draw firm conclusions about programs because data may compare different program attributes. This is a common problem that arises when comparing programs, especially across countries. CalRecycle still included the information as it is the best information available to suggest expected costs and encourage efforts to establish common metrics.

CalRecycle observed some common themes among the programs researched. All programs reviewed seek to provide a secure system for pharmaceuticals and programs in other countries use pharmacies as collection points. It appears that other countries do not have laws on par with the U.S. Controlled Substance Act, which only allows law enforcement officials to handle controlled substances (e.g., narcotics). This means that outside of the United States, pharmacies can serve as convenient consumer drop-off locations for all types of pharmaceuticals. This may change once regulations are promulgated as part of the recently passed *Secure and Responsible Drug Disposal Act of 2010*, (also see Section II, *2. National Programs*, Federal Legislation and Regulations below). Also, most countries with collection programs have significant industry participation, including at least some industry funding, with the exception of Sweden, which operates collection through nonprofit, state-run pharmacies. Additionally, Australia has a primarily government-funded program.

When the private sector funds and manages collection and safe disposal of drugs, such a program is referred to as a product stewardship program. Product stewardship programs offer a private sector approach to waste management. Appendix B offers cost information on various pharmaceutical programs

and this preliminary information suggests a generally lower cost per capita for those programs with greater industry funding. Overall, however, CalRecycle is not able to draw any specific conclusions about which of these programs are most effective due to data gaps and a lack of detailed information about the programs to ensure a fair comparison.

1. International Guidelines and Programs

WORLD HEALTH ORGANIZATION

- The **World Health Organization**[36] issues guidelines for pharmaceuticals management during and after emergencies. These guidelines state that if take-back programs are not available and pharmaceuticals are treated prior to disposal by waste immobilization, it is acceptable to dispose of controlled substances in engineered or permitted landfills.[37] Immobilization refers to either encapsulation or inertization (removing the packaging materials from the pharmaceuticals, grinding pharmaceuticals, and mixing them with water, cement, and lime).

AUSTRALIA

- **Australia: Return Unwanted Medicines Project.** This national program allows consumers to return pharmaceuticals to any pharmacy across Australia. Most costs are covered by the Department of Health and Aging with limited support from the pharmaceutical industry. Preliminary information on costs per capita suggest the project is on par with other international programs, however it has a fairly low per capita collection rate in comparison. This program collects and makes available information on commonly returned medicines, reasons for return, and conducts targeted education campaigns. Consumers do not have to distinguish which drugs are controlled substances because pharmacies accept all types and then pharmacies follow specific disposal instructions for controlled substances or "Schedule 8 medicines." The protocols for pharmacies, which must use approved collection bins, are available online at www.returnmed.com.au/.

EUROPEAN UNION

The European Union Directive 2004/27/EC, Article 127b requires that, "Member States shall ensure that appropriate collection systems are in place for medicinal products that are unused or have expired."[38] As a result, numerous programs exist and several have data available as indicated below.[§§§§] Additionally, Article 54j of this same directive has labeling requirements so information about collection programs appears on pharmaceutical packaging.

[§§§§] The report, *Pharmaceuticals in the environment — Result of an EEA workshop*, 2009 (available: www.eea.europa.eu/publications/pharmaceuticals-in-the-environment-result-of-an-eea-workshop) includes a summary of European programs and says the return rate in Switzerland is very high, followed by Ireland, Luxembourg, Sweden, and France. However, the report does not provide specific information to include in this legislative report.

- **France: Cyclamed Program.** This national program allows consumers to return pharmaceuticals to local pharmacies for safe disposal. The program is funded and managed by the private sector (industry, pharmacies, and wholesalers). It stands out for having relatively high per capita collection and participation rates as noted in Appendix B. Also, the amount of pharmaceuticals collected, reported in terms of with and without packaging, indicates that it is very important to understand the extent to which packaging is included in measurements as it can significantly impact the collection rates. This program offers more information on its performance than many other programs.
- **Portugal: Valormed Program.** This national program allows consumers to return unused pharmaceuticals to local pharmacies for safe disposal. It is funded by members of pharmaceutical associations, including local pharmacies, manufacturers, distributors and chemical and pharmaceutical importers. This particular product stewardship program places an eco-fee of one cent on each package placed in the market. The program stands out as having a fairly high per capita collection as compared to other programs in this section. Significant information gaps include costs and to what extent the collection includes packaging.
- **Spain: SIGRE Program.** This national program allows consumers to return unused pharmaceuticals to local pharmacies for recycling or safe disposal. It is managed by SIGRE, a nonprofit funded by members of the pharmaceutical industry based on volume of sales. The program stands out as having fairly high per capita collection and is a product stewardship model that uses a stewardship organization. Significant information gaps include costs and to what extent the collection metrics include packaging.
- **Sweden: Apoteket AB Program.** This national program allows consumers, along with other types of facilities such as care centers, dentists, hospitals, veterinarians, and farmers, to return leftover pharmaceuticals to the state-owned, nonprofit retail pharmaceutical chain. The program stands out for being government managed and financed, and for having higher reported costs and higher collection rates. Significant information gaps include how the collection rate is calculated given the broader scope of the program and to what extent collection metrics include packaging.

CANADA

Health Canada reports on pharmaceutical programs in 13 provinces and territories. It specifically mentions four of these programs as achieving relatively high collection rates in either total amounts collected or on a per capita basis. These are noted below, along with the program in Ontario that started in July 2010, and offers some of the latest thinking on program design:

- **Alberta ENVIRx Program.** This province-wide program allows consumers to return pharmaceuticals to a majority of local pharmacies for safe disposal. It is mainly funded by industry, but also by small grants from the provincial government. The program stands out for being voluntary. Significant information gaps include costs and to what extent collection metrics include packaging.
- **British Columbia PCPSA Program.** This province-wide program allows consumers to return pharmaceuticals to a majority of local pharmacies for safe disposal. The program is managed by a stewardship organization called the Post Consumer Pharmaceutical Stewardship Association (PCPSA) and is funded by industry. The program stands out for having more complete reporting and cost information, and relatively low collection rates and high costs for a product stewardship program.

Significant information gaps include to what extent collection metrics includes packaging, which can affect per capita costs and collection rates.

- **Nova Scotia Medication Disposal Program.** This province-wide program allows consumers to return pharmaceuticals to local pharmacies for safe disposal. The program is administered by the Pharmacy Association of Nova Scotia (PANS) and funded by industry. Pharmacies have the option of participation and, according to PANS, all choose to participate. Because the program is voluntary and does not have reporting requirements, minimal information is publicly available. However, Health Canada reports that it has a relatively high per capita collection as compared to other Canadian programs.

- **Ontario Orange Drop Program.** This province-wide program covering 22 hazardous and special wastes, including household pharmaceuticals started in July 2010. New regulations defined the term "used consumer pharmaceuticals" to cover pharmaceuticals sold by retail establishments and returned by consumers. Only these pharmaceuticals can be returned to pharmacies. Pharmacies follow newly created rules for used consumer pharmaceuticals that are less stringent than rules established for pharmaceuticals that are returned to suppliers in a reverse distribution process; the latter requiring complex tracking of ownership. Consumers push pharmaceutical waste into a one-way collection container at their local pharmacy. The waste is picked up on a regular schedule or upon request when the bin is full. The program has been administered by Stewardship Ontario and funded by industry; however, starting in fall 2010, the province will begin to provide funding to municipalities for management of this and several other programs. Ninety percent of pharmacies participate and accept unused/out-of-date pharmaceuticals from consumers. Additionally, the program holds hundreds of collection events for multiple products and uses household hazardous waste depots as collection sites. The program has established a baseline and targets initially call for collecting 47 percent of available pharmaceuticals, increasing to 74 percent in 5 years.[39]

- **Saskatchewan Waste Disposal Program.** This province-wide program allows consumers to return pharmaceuticals to participating local pharmacies for safe disposal. The program is managed by the Pharmacists' Association of Saskatchewan and funded by community pharmacies. This program is voluntary and does not have reporting requirements so minimal information is publicly available, but Health Canada reports that it has a relatively high per capita collection as compared to other Canadian programs.

2. National Programs

In addition to California laws and policies (see Section I, *4. Current status of regulations, statutes, and policy*), there are several national efforts to address safe management of unwanted home-generated pharmaceuticals. These are found in federal policies, laws, and regulations, along with nationally-based efforts by nonprofits, including those identified below. As noted, there are no nationwide home-generated pharmaceutical waste collection programs in the United States; waste collection is a state and local managed program.

FEDERAL GUIDELINES

- The **White House Office of National Drug Control Policy** issued in October 2009 new guidelines, *Proper Disposal of Prescription Drugs* (federal guidelines), to educate consumers about safe methods of pharmaceutical disposal.[40] These guidelines first recommend participating in take-back programs, if available. When that option does not exist, it is recommended that drugs be removed from original containers and mixed with undesirable substances (like coffee grounds or cat litter), and then sealed in an impermeable container before throwing the unused drugs in the trash.

  These federal guidelines address the concern of removing unwanted pharmaceuticals from households to minimize drug abuse. When the policy is followed, unwanted pharmaceuticals are placed in containers and are undistinguishable from other containers in household trash, making it more difficult for someone to find and abuse them. Furthermore, disposal in household trash is convenient and removes pharmaceuticals from homes at no additional cost to consumers. Several states actively promote the federal guidelines in their programs and provide information to consumers about how to hide and disguise unwanted pharmaceuticals in household trash, when local collection programs are not available (see Section IV, *3. State Programs* below). Additionally, the U.S. Food and Drug Administration developed educational materials for consumers on these guidelines.[41]

  By recommending disposal in household trash, the federal guidelines alleviate the concerns of improper disposal of pharmaceutical waste into sewer systems that results in pharmaceuticals entering waterways and drinking water. On the other hand, a main drawback with the federal guidelines is that pharmaceuticals can then be deposited in landfills where they may eventually be able to leach into ground and surface waters. However, CalRecycle received numerous comments about this issue and reports to date (several of which are funded by industry) indicate this is a minor impact.

FEDERAL LEGISLATION AND REGULATIONS

While no national laws directly govern home-generated pharmaceutical waste, once home-generated pharmaceutical waste is collected at a consolidation point, it is subject to at least four national laws.

- The **U.S. Controlled Substances Act** regulates the manufacture and distribution of narcotics, stimulants, depressants, hallucinogens, anabolic steroids, and chemicals used in the illicit production of controlled substances, and defines who may possess controlled substances. Controlled substances must be collected by sworn law enforcement officers (pharmacies may only take back uncontrolled substances).

  Program managers in California and in other states have viewed the federal Controlled Substances Act as a barrier to collection because it limits unsorted returns of controlled substances to law enforcement, which generally is less convenient than collection programs at local pharmacies. Consumers often times do not know and cannot easily determine if a drug is a controlled substance. Finally, in some regions of California, local jurisdictions report that law enforcement has placed higher priority on other responsibilities and has been unwilling to participate in collection activities. Additionally, residents are not as familiar with, and in some cases are reluctant to visit, law enforcement locations.

- In October 2010, President Obama signed into law the **Secure and Responsible Drug Disposal Act of 2010** (United States Senate, S. 3397, 111th Congress). This law gives the Attorney General authority to promulgate new regulations, within the framework of the Controlled Substances Act, which will

allow patients to deliver unused pharmaceutical controlled substances to appropriate entities for disposal in a safe and effective manner consistent with effective controls against diversion. This law is intended to make it easier to collect and dispose of controlled substances while preventing illegal diversion of drugs. The process to develop new regulations could take a few years and, until that time, it is not completely known what the outcome will be. These new regulations are expected to impact collection programs in California since more program types could potentially begin collecting controlled substances.

- The **Resource Conservation and Recovery Act (RCRA)** governs the management of hazardous wastes at the federal and state levels, including some waste drugs. RCRA excludes from regulation pharmaceutical waste produced by individuals in their homes. States can choose to be more stringent, as California has (California Code of Regulations Title 22, Section 66261.101). However in this case, if a home-generated pharmaceutical is not a RCRA-regulated hazardous waste, it is not subject to California hazardous waste control laws. Thus, home-generated pharmaceutical waste is not regulated as hazardous waste in California unless it is comingled with other hazardous waste. This often occurs at household hazardous waste facilities where it is a general practice to comingle these wastes.
- **Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180)** determine how to classify and transport chemotherapeutic and some pharmaceutical wastes. However, household waste, which includes home-generated pharmaceutical waste, is excluded from these requirements and the HMR would apply only if home-generated pharmaceutical waste is comingled with hazardous waste.
- The **Health Insurance Portability and Accountability Act (HIPAA)** provides a federal floor of privacy protections for an individual's health information when that information is held by a covered entity or by a business associate of the covered entity. With respect to home-generated pharmaceuticals, HIPAA concerns are associated with patient information that may be contained on any packaging that is returned along with the waste.

NATIONWIDE EFFORTS

- The **American Medicine Chest Challenge** is a nationwide take-back event that occurred on Nov. 13, 2010.[42]
- The **Drug Take-Back Network** provides a clearinghouse of information on pharmaceutical take-back programs across the United States covering national, state and local programs. More information is available at: www.takebacknetwork.com
- The **National Prescription Drug Take-Back Campaign** was coordinated by the DEA to remove potentially dangerous controlled substances from medicine cabinets across the nation. State and local law enforcement agencies collected more than 242,000 lbs of drugs from more than 4,000 sites in all 50 states at this first-ever nationwide program held Sept. 25, 2010.[43]
- The **U.S. Postal Service (USPS) Prescription Mail Back Pilot Program** is intended to provide an estimated 780,000 veterans in Baltimore, Md., Washington, D.C., and West Virginia the opportunity to safely dispose of expired and unused prescriptions and help the environment. The program is being administered by the USPS and the U.S. Department of Veterans Affairs and allows veterans to mail outdated, unwanted medicine to federally-approved facilities where it is safely destroyed. Veterans receive specially designed, postage-paid envelopes and instructions with their prescription fulfillment. Expired and unused pharmaceuticals placed in the special packaging can be dropped in familiar blue

USPS collection boxes or at post offices. The envelopes are delivered to facilities regulated and approved by the U.S. Environmental Protection Agency (EPA) and DEA. Pharmaceuticals from this and other similar mail-back initiatives are destroyed in accordance with EPA and DEA standards, including cataloguing and use of incineration, chemical or thermal processes.[44]

- The **Product Stewardship Institute (PSI)** works with stakeholders nationwide to develop product stewardship approaches for the end-of-life management for many difficult-to-manage unwanted/waste products, including pharmaceuticals. The main goals of the PSI multi-stakeholder dialogue are to increase awareness and to create a national, sustainable system for the end–of-life management of unwanted/waste pharmaceuticals. [45]

3. State Programs

At this point, several states have undertaken pilot programs to test methods for collecting home-generated pharmaceuticals. Washington and Maine's pilot programs stand out, for example, for being complete and provide fairly detailed information about costs and collections rates. Overall, among all pilot programs researched, there is a need for:

- Sustainable funding;
- Safe and legal disposal for home-generated pharmaceuticals;
- Convenient collection through pharmacies, other collection sites, and mail-back programs; and
- Amendment to the Controlled Substances Act to allow for the collection of prescribed controlled substances at pharmacies.

In addition to pilot programs, some states promote the National Drug Control Policy (see "federal guidelines" in Section IV, *2. National Programs* above) and also allow home-generated pharmaceuticals to be incinerated at waste-to-energy facilities with other municipal solid waste.

Several state programs are listed below. These programs exclude controlled substances, unless noted:

- **Colorado:** The Colorado Department of Public Health and Environment and a consortium of concerned organizations have launched a pilot program, to run through 2011. This program seeks to provide a secure and environmentally responsible way for people to dispose of unwanted medicines, excluding controlled substances. Tamper-resistant collection boxes are available at 10 locations around the Denver metro area, including several stores, two county health department offices, and a health clinic. Funding is provided by federal, state and local government agencies (e.g., public health, water and environmental agencies), and pharmaceutical and nonprofit organizations.[46]
- **Florida:** The Florida Department of Environmental Protection promotes the National Drug Control Policy guidelines through educational materials. Brochures in English and Spanish inform Florida residents not to flush unused pharmaceuticals down the drain and explain how to dispose of unwanted pharmaceuticals in household trash. The state distributes information to consumers through pharmacies and through its website on medications management: www.dep.state.fl.us/waste/categories/medications/default.htm. This website includes research papers, presentations and disposal guidelines. All household-generated pharmaceutical waste, including waste from collection programs, and pharmaceuticals that are evidence or confiscated by law enforcement, are allowed to be burned in Waste-to-Energy (WTE) facilities whether or not they would otherwise be

hazardous waste. WTE permit conditions allow for pharmaceuticals to be burned so long as they do not exceed 3 percent of total throughput.[47]

- **Iowa:** The Iowa TakeAway program aims to provide the public with a safe, easy way to properly dispose of unwanted and expired medications, excluding controlled substances. TakeAway uses community pharmacies across the state as take-back sites. Some participating pharmacies also sell TakeAway envelopes, pre-addressed, pre-postage paid large envelopes that can be taken into the home, filled with unused and expired medicine, and mailed through the United States Postal Service to a disposal facility. Funding was provided through Iowa Department of Natural Resources grants to the Iowa Board of Pharmacy, which worked closely with the Iowa Pharmacy Association, to offer the TakeAway pilot program. The $165,000 grant paid for collection in 357 pharmacies and as of May 2010, 2,550 lbs were collected and destroyed (this does not count partially filled bins).[48, 49]

- **Maine:** The Safe Medicine Disposal for ME Program is a statewide pilot program for the disposal of unused household medications using a mail-back return envelope system. [50] The program was established through state legislation and implemented in 2007 with a $150,000 grant from the EPA's Aging Initiative. The program was authorized to handle both controlled and non-controlled medications. All drugs collected undergo high-heat incineration, according to the procedure already established for Maine's law enforcement drug seizures. Costs were $18.79/mailer, including both actual and in-kind costs during the start up (phase I and II); long-term costs are anticipated to be $7.50 /mailer (phase III). The average weight of a mailer with drug waste is seven ounces. A report on the statewide mail-back model concludes that mail-back offers "an element of confidentiality and anonymity not found with in-person take back programs and is the least burdensome of all models in terms of consumer access and utilization." It further states that "Maine's citizen mail-back program has demonstrated that this approach is not only feasible, but effective." More recently, the Maine Department of Environmental Protection reported on research that found leachate in three lined landfills that contained a large variety of pharmaceuticals and personal care products.[51]

- **Massachusetts:** The Massachusetts Department of Environmental Protection has a comprehensive program to study and monitor pharmaceuticals in state waters. Department personnel are working with related agencies and stakeholders to reduce the amount of medications going to wastewater treatment plants, and to keep the public informed about the issues. Additionally, Massachusetts also promotes National Drug Control Policy guidelines, calling for participation in local collection programs, and if none are available then disposing of pharmaceuticals in household trash using the federal guidelines. More information is available at: www.mass.gov/dep/toxics/stypes/ppcpedc.htm.[52]

- **New York:** The New York Drug Management and Disposal Act (2008) requires stores that sell pharmaceuticals, vitamins, supplements, and over-the-counter medications to display posters about how to properly dispose of drugs as part of the "Don't Flush Your Drugs" public awareness campaign. Instead of flushing medicines, households are encouraged to take advantage of community drug take-back programs that collect drugs at a central location for proper disposal. Collection event organizers must develop a collection plan, work with local law enforcement to secure the drugs at the collection event and obtain a variance, which allows the collected pharmaceuticals to be incinerated at waste-to-energy facilities within the state. Collection events to collect controlled substances must be approved by the New York State Department of Health, Bureau of Narcotic Enforcement. Households that are not able to take unwanted pharmaceuticals to collection events are advised to place their unused, unwanted, or expired drugs in the trash, taking care to destroy or disguise them to avoid misuse or misdirection with the suggestion of adding water, salt, ashes, or coffee grounds to unused medications

before placing them in the trash. Detailed instructions and suggestions are available on the New York Department of Environmental Conservation website www.dontflushyourdrugs.net.[53]

- **Texas**: To help ensure unused pharmaceuticals do not enter a wastewater system, the Texas Commission on Environmental Quality is conducting a study and submitting recommendations to the Texas Legislature on the methods currently used in the state to safely handle and dispose of pharmaceuticals, medical sharps, and other potentially dangerous waste. The recommendations also suggest alternative methods used for that purpose, including the methods used in other states; and the effects of the various methods on public health and the environment. The report is due in December 2010.[54]
- **Washington:** To address the need for a safe way to dispose of unwanted medicines, excluding controlled substances, a coalition of government, nonprofit, and business partners began a 2006 Washington state pilot program called Pharmaceuticals from Households: A Return Mechanism (PH:ARM). The program took place at Group Health Cooperative, a regional healthcare organization in Washington; Bartell Drug, a Western Washington retail pharmacy chain; and two boarding homes. Key findings of the PH:ARM pilot program are:
    - Medicine return programs can provide environmentally sound disposal of medicines.[55]
    - Returning medicines to a pharmacy with proper oversight and strict protocols can be safe and secure for any type of medicine, including controlled substances.
    - Medicine return programs are cost-effective to operate.
    - The Controlled Substances Act should be changed to allow collection of legally prescribed controlled substances at pharmacies.
    - A statewide program could collect a substantial amount of unwanted medicines.
    - Pharmacy-based medicine return is convenient and effective.
    - Community demand for safe disposal of medicines is high.
    - Sustainable funding is needed for a statewide medicine return program.

Additionally, many local governments and groups of states host collection events. For example, in Maryland, seven counties collect pharmaceuticals and a regional program is under way with the EPA and four states that focus on the Potomac River watershed.[56]

PROPOSED AND ENACTED STATE-LEVEL LEGISLATION

Several states (Florida, Maine, Maryland, Minnesota, Oregon, Rhode Island, and Washington) have proposed product stewardship legislation for pharmaceuticals, but as of September 2010, none have passed as such. Minnesota enacted House File 1217 that enables various parties including licensed HHW facilities and county collection programs to have possession of prescription drugs for the purpose of disposal.

PSI tracks pharmaceutical take-back legislation and is a source for more current information. See: www.productstewardship.us/ (select: products, pharmaceuticals).

V. Potential Options for Further State Action

Note: In response to comments on the Background Paper for the July 2010 stakeholder workshop, CalRecycle staff edited this section so that Options are divided into regulatory and financing options in this revised Background Paper, and additional information is provided about the consequences of adopting any of these options. As with the earlier version, this background paper does not include any CalRecycle recommendations regarding the options

This section includes a range of potential options for further state action with regard to pharmaceutical collection programs. Options can be categorized into two groups -- regulatory and funding. Each of these is described briefly here and then in more detail below.

There are two regulatory options:

Option 1. Continue Current Use of Model Guidelines maintains the status quo and entails using voluntary federal guidelines and the current California Model Guidelines. The former teaches residents how to properly dispose of drugs in household trash if local collection programs are not available, while the California Model Guidelines address safe practices of home-generated pharmaceutical collection programs.

Option 2. Establish Clear State Agency Roles and Responsibilities, Improve Model Guidelines and Enforcement, and Convert Guidelines to Regulation relies on statutory changes to establish clear state roles and responsibilities and to provide direction to resolve several implementation challenges. It also would convert the Model Guidelines into state regulations.

These are followed by two funding options that address the need for long-term program funding, which is essential for establishing more collection programs and maintaining existing ones.

Option 3. Implement Product Stewardship provides program financing through a private sector approach, with government oversight. This is commonly referred to as product stewardship. Manufacturers or drug brand owners would design, manage, and finance a statewide program, while state government would oversee successful program implementation and enforcement.

Option 4. Create State Collection Program Supported by Advanced Disposal Fee relies on a fee paid by consumers at the point-of-purchase to support program activities (such fees typically are known as "advanced disposal fees"). The fees would be used to implement a state government program, in which a designated state agency would design, manage, and enforce the program, in addition to collecting and dispersing funds.

For each of these four options, CalRecycle describes in more detail below their potential impacts, arranged by the:

- Four evaluation factors specified in SB 966 (safety, accessibility, cost-effectiveness, and efficacy);
- Challenges and barriers discussed previously in this paper (Expense of Safe Collection, Lack of Public Awareness and Participation, Lack of Sustainable Funding, Lack of Goals, Unclear Requirements, Policies and Authorities); and
- Environmental impacts addressed by SB 966.

Options 2, 3, and 4 would require new legislation to be implemented. CalRecycle also recognizes that there is not agreement among stakeholders on preferable types of collection programs, nor on state agency roles and responsibilities. Some stakeholders advocate that unless federal regulations change (see Section IV, *2. National Programs*, Federal Legislation and Regulations) so that pharmacies and mail-back programs may collect controlled substances, law enforcement should collect all home-generated pharmaceuticals. Otherwise drugs would need to be sorted to follow the law, but it is hard to distinguish between a controlled and uncontrolled substance so these programs are expensive. Other stakeholders argue that mail-back programs should be the primary program type allowed because they do not face these same restrictions and because they offer convenient collection, safety, and privacy. Others argue that all collection options should be available.

1. Regulatory Options

OPTION 1. CONTINUE CURRENT USE OF MODEL GUIDELINES

Under this option the state would maintain the voluntary Model Guidelines, and where local programs do not exist, the state would encourage consumers to follow federal guidelines.

This option thus would encourage programs (such as at pharmacies and HHW facilities) to follow the Model Guidelines and allow consumers to continue to dispose of pharmaceuticals in their household trash that goes to landfills. Consequently, some pharmaceutical chemicals would likely be found in landfill leachate, although this appears to be a minor pathway for releases to the environment.[*****]

This option does not provide funds for public education; some other states such as New York do provide funding for education programs. If an organization (e.g., pharmaceutical manufacturers, brand owners, government) educated consumers on proper disposal, including the federal guidelines on how to dispose drugs in household trash, many of the impacts described below could be mitigated. This could be done without additional collection costs, without legislation, and result in removing unwanted drugs from households, but would not meet environmental objectives to significantly decrease pharmaceuticals released to the environment.

In contrast, if the primary concern of the Legislature is to provide convenient long-term collection opportunities for home-generated waste and to minimize illegal diversion of such waste, then other options listed in this section should be considered.

[*****] CalRecycle is aware of only a few studies regarding concentrations of pharmaceuticals in leachate from U.S. landfills, and few of these are peer-reviewed. In general, they indicate that most pharmaceuticals in the environment are the result of human excretion as opposed to being from home-generated pharmaceutical waste, that pharmaceuticals may be found in generally low concentrations in landfill leachate discharged to wastewater treatment plants, and the latter could be viewed as a minor pathway by which pharmaceuticals reach the environment.

POTENTIAL IMPACTS:

Safety: No change from current level. Illegal diversion could still occur at waste disposal collection points (e.g., scavengers at trash bins, employees at materials recovery facilities). However, the "treatments" described in the federal guidelines could be adequate if consumers follow them so that drugs would be rendered non-consumable and hidden in household trash.

Accessibility: No change from current level. A wide range of collection programs could continue as they currently exist, but many consumers would remain unaware of collection options or would not participate in available programs.

Cost-effectiveness: No change from current level. This option would not reduce collection and management costs from current levels.

Efficacy: No change from current level. Collection programs could continue to explore ways of providing more cost-effective solutions without additional constraints or requirements. But this option would not significantly increase collection unless there was significant public education; as a consequence, pharmaceuticals would continue to be stored at home, disposed of in landfills, or flushed down toilets, and would eventually enter streams and groundwater. Collection levels would likely remain quite low compared to the total amount of home-generated pharmaceutical waste.

Expense of Safe Collection: No change from current challenge. Because the Model Guidelines are voluntary, some requirements would continue to be ignored in order to reduce costs.

Lack of Public Awareness and Participation: No change from current challenge. Would not address need for increased education. Greater confusion may arise if local governments adopt ordinances resulting in highly variable approaches across the state.

Lack of Sustainable Funding: No change from current challenge. Places no additional costs on state government, but would not address issue of insufficient funding or lack of sustainable funding source. Local governments would need to continue to find ways of funding these collection programs.

Lack of Goals: No change from current challenge.

Unclear Requirements, Policies and Authorities: No change from current challenge. Does not require new legislation. State agency roles and responsibilities would remain confusing and program managers would not have clear requirements to follow.

Environmental Impacts: No change from current impacts. Would not address potential impacts, such as bioaccumulation, sensitive species and/or synergistic effects, from wastewater treatment discharges (including materials originating from leachate). If excretion is the main cause of water contamination, which research supports, then this suggests a different type of approach is needed (such as designing pharmaceuticals to be better metabolized by consumers, encouraging practices that reduce over-subscribing prescriptions, and other source-reduction approaches).

OPTION 2. ESTABLISH CLEAR ROLES AND RESPONSIBILITIES, IMPROVE MODEL GUIDELINES AND CONVERT TO REGULATIONS, AND PROVIDE ENFORCEMENT AUTHORITY

This option focuses on strengthening the Model Guidelines by establishing clear state agency roles and responsibilities, making the Model Guidelines mandatory, and providing authority to enforce them.

A key element of this option is to provide clear legislative authority and "clean up" confusing laws and regulations. For example, one of the biggest points of confusion is that pharmaceutical discards can be classified and regulated in multiple ways depending on how and where they are collected and managed. The Legislature could define home-generated pharmaceutical waste and a level of management for home-generated pharmaceuticals that would provide needed safety but would be less stringent than requirements for managing medical waste. Further, the Legislature could define at what point, if any, consolidated home-generated pharmaceutical waste should be considered medical waste and handled as such. Providing needed safety would include remaining consistent with federal controlled substances laws such as the Controlled Substances Act. Legislation could also identify a state agency to develop regulations that codify current voluntary Model Guidelines and require collection and disposal programs to follow them. Additionally, the Model Guidelines could be modified to allow for additional practices, provided they offer equivalent safety (e.g., new technologies might offer lower-cost alternatives to the current two-key system used in pharmacies). The intent of these activities would be to establish clear state agency roles and responsibilities, and to improve enforcement and implementation of home-generated pharmaceutical collection and disposal programs.

As noted, under this option collection programs would be required to follow Model Guidelines to ensure safety. The Model Guidelines have been the officially sanctioned home-generated pharmaceutical waste collection guidelines in California since November 2008 and serve as a platform for establishing regulations. Additionally, out of 256 existing collection programs and events, there are not any reported signs of illegal drug diversion so it appears the Model Guidelines offer adequate safety. Legislation would have to delineate who is responsible for properly managing collected drugs and provide the lead state agency with sufficient authority to take enforcement action against non-complying entities.

Option 2 assumes no additional funding for individual collection programs would be made available, although the designated state agency would require additional resources to develop and implement regulations. Options for program funding are covered in Option 3 (private sector managed product stewardship) and Option 4 (state government managed advanced disposal fee).

POTENTIAL IMPACTS:

Safety: The percentage of programs meeting the Model Guidelines could rise if the guidelines became mandatory. However, a potential unintended result could be fewer programs, if the Model Guidelines were viewed as too onerous.

Accessibility: Because requirements will be clearer, the number of collection programs may increase to provide consumers with greater accessibility. However, the overall number of programs may not increase if the costs associated with meeting the Model Guidelines are too high. In addition, if restricted to law enforcement, accessibility would depend on the willingness of law enforcement entities to participate.

Cost-Effectiveness: Mandatory implementation of the Model Guidelines could result in higher costs and lower cost-effectiveness. If clarification of the Model Guidelines identified additional options or flexibility, costs could be reduced.

Efficacy: Some increase in collection is possible, but as long as programs are voluntary, collection levels would likely remain quite low compared to the total amount of home-generated pharmaceutical waste.

Expense of Safe Collection: Mandating use of the current Model Guidelines will likely make this challenge worse as all programs must meet all the criteria.

Lack of Public Awareness and Participation: No change from current challenge.

Lack of Sustainable Funding: Could place additional costs on state government for regulatory and enforcement activities. Would not address the issue of insufficient funding or lack of a sustainable funding source. Local governments would need to continue to find ways to fund these collection programs.

Lack of Goals: No change from current challenge.

Unclear Requirements, Policies and Authorities: Would provide an opportunity to update the Model Guidelines and set clear, consistent and enforceable standards. Could better define state agency roles and responsibilities through legislation or regulation and avoid on-going debate among state entities.

Environmental impacts: Since this option assumes no additional funding would be made available and the number of collection sites would not increase significantly, pharmaceuticals would continue to be stored at home, disposed of in landfills or flushed down toilets, and eventually enter streams and groundwater.

2. Funding Options

OPTION 3. IMPLEMENT PRODUCT STEWARDSHIP

Under this option, legislation would mandate a private-sector designed and managed producer responsibility approach for pharmaceuticals. This also would provide the authority for state oversight to ensure a level playing field, and address issues of state agency roles and responsibilities so that pharmaceutical collection is less confusing and more streamlined.

Because this approach is not yet used widely in California, it bears additional explanation here. Product stewardship programs use a private-sector approach to managing discards.[57] Product stewardship is a shared responsibility approach that could provide for safe, accessible, and cost-effective end-of-life management of home-generated pharmaceuticals. Product stewardship programs are working successfully in the United States, Canada, Europe, and elsewhere for products ranging from computers to paint to pharmaceuticals. In California 100 local jurisdictions have already adopted product stewardship resolutions for a variety of products, indicating growing interest and support.[58] CalRecycle has adopted a Strategic Directive on producer responsibility and adopted an Extended Producer Responsibility Framework Document in January 2008.[59] Additionally, two product stewardship laws were enacted in 2010 to establish private-sector managed and funded recycling programs for carpet (AB 2398, Perez, Chapter 681, Statutes of 2010) and architectural paint (AB 1343, Huffman, Chapter 420, Statutes of 2010).

Conceptually, this approach appropriately places the primary responsibility for pharmaceutical management with the pharmaceutical manufacturer and the consumers who use them, rather than ratepayers and local governments, which currently spend more than $600,000 per year on what is likely a

small percentage of all home-generated pharmaceutical waste.[†††††] In other words, those who benefit from pharmaceuticals pay for pharmaceutical waste management costs. Using less material in the design of products, often called source reduction, prevents waste and can provide a great environmental benefit. A potential source reduction benefit could emerge from the closer involvement of pharmaceutical manufacturers with drug waste. Manufacturers could gain insights they currently lack regarding the extent, scope, and magnitude of drug waste. To reduce costs and negative impacts they may change their manufacturing, packaging, and prescribing/dispensing practices. For instance, pharmaceutical manufacturers may learn that certain medications intended to be taken completely are typically returned with portions unused. In this case, education practices while prescribing/dispensing may be improved in order to reduce industry-funded disposal costs. Likewise, insurers could use information gleaned from collection programs to determine optimal dispensing practices.[60]

Full product stewardship programs are industry-led, giving producers or manufacturers the flexibility to design and implement their own programs, with the state or federal governments' role focused on setting ground rules and providing oversight. Program costs are covered in the product price so those who use the product pay for its full cost. Producers are generally able to implement programs either individually or by joining together with other producers through a product stewardship organization that collects, properly manages, and interacts with the state oversight agency on its behalf. Product stewardship programs are financed by the private sector and government does not collect any taxes. Rather, managing materials becomes another business cost that is incorporated into product price, similar to any other costs.

Producers (or their product stewardship organization) plan and implement collection programs, and later provide for an independent audit and submit progress reports to the lead state agency. For example, the producer would select the collection system that it determines to best achieve goals for the lowest cost. It could be through a willing pharmacy, or through law enforcement, at events, through mail-back, or some combination of these. As long as goals and laws are met, state government would not be involved, except in an oversight capacity and to ensure all producers participate.

POTENTIAL IMPACTS:

Safety: An adequately funded and well coordinated, cooperative approach could result in safer handling of home-generated pharmaceutical waste. Better financing, consumer education, and more participation would likely increase the level of secure pharmaceutical management to prevent illegal diversion.

Accessibility: Would likely result in increased consumer accessibility.

Cost-Effectiveness: Creates an incentive for producers to more efficiently collect pharmaceuticals and considers product design changes that reduce management costs.

Efficacy: Private sector programs can adapt more readily to changes in laws and market conditions and modify their program to maximize effectiveness. A more comprehensive and cooperative approach could capture significantly more home-generated pharmaceutical waste.

Expense of Safe Collection: This approach may find new ways to approach the current Model Guidelines.

[†††††] A cost of $600,000 per year is based on CalRecycle survey results from local governments (including mailback, events, and 206 continuous collection programs. Since 51 percent of all programs did not report staff time, and if current programs address only 5 percent of home-generated pharmaceuticals, then costs for collection throughout California would be much higher.

Lack of Public Awareness and Participation: Efforts to increase public awareness and participation would be part of the product stewardship program.

Lack of Sustainable Funding: Offers an equitable system where those who benefit from a product pay for its full costs. The option creates a new role for pharmaceutical manufacturers, who may resist additional responsibility and additional costs. It would provide sustainable funding for all program activities and could reduce financial burdens on local governments. Additional requirements on state government for oversight activities would be funded by industry through the product stewardship organization.

Lack of Goals: This option would likely have goals to work toward as part of its framework.

Unclear Requirements, Policies and Authorities: Requires new legislation that may be difficult to enact. Would minimize government bureaucracy and provide for clear government regulatory roles and responsibilities that can reduce program implementation costs.

Environmental Impacts: Less home-generated pharmaceutical waste would enter the environment. If a product stewardship program provides incentives to reduce releases into the environment, then it could help drive the creation of new and less environmentally harmful drugs. For instance, a manufacturer's share of disposal fees could be reduced proportionate to their production of pharmaceuticals that are metabolized the most and cause the least environmental impact.

OPTION 4. CREATE STATE COLLECTION PROGRAM SUPPORTED BY ADVANCED DISPOSAL FEE

CalRecycle already manages several programs using an advanced disposal fee (ADF). Under these programs, consumers pay a fee at the time of purchase that is deposited in a fund managed by state government. Funds from this account are used to finance a collection program as well as to support the state agency resources needed to collect fees and implement the program. CalRecycle, or another state agency, would establish the requirements for service providers participating in the collection program, certify or register service providers, pay service providers who collect the products covered under the program, and oversee compliance and enforcement.

POTENTIAL IMPACTS:

Safety: An adequately funded and well regulated program could result in safer handling of home-generated pharmaceutical waste. Better financing, consumer education, and more participation would likely increase the level of secure pharmaceutical management to prevent illegal diversion.

Accessibility: An ADF option could utilize any or all of the collection program types currently used, or could mandate more specific requirements. This option would likely result in increased consumer accessibility as more programs were created to tap into the funds collected through the ADF.

Cost-Effectiveness: There would be less incentive to be innovative or to more efficiently collect pharmaceuticals if the state requires specific method(s) and/or pays a standardized processing/collection payment to service providers. ADF programs are known to achieve high collection rates, but are expensive

compared to a private sector designed and managed programs, such as those using a product stewardship approach. The approach could also increase government bureaucracy.‡‡‡‡‡

Efficacy: Private sector service providers would have an incentive (processing/collection payments) to create new programs and expand existing programs to gather more materials. A more comprehensive and regulated approach could capture significantly more home-generated pharmaceutical waste.

Expense of Safe Collection: This approach could subsidize safe collection methods enough to make more programs feasible.

Lack of Public Awareness and Participation: Private-sector service providers would have an incentive (processing/collection payments) to educate the public about the services they provide and to compete for home-generated pharmaceutical waste.

Lack of Sustainable Funding: This option would provide sustainable funding for all program activities and place significant additional costs on state government for regulatory, fiscal, and enforcement activities funded by the ADF. It could greatly reduce burden on local governments, which currently spend more than $600,000 per year, and would create a visible fee on consumers which may be misinterpreted as a tax. Given a fee would be tied to a specific service, it would not be a tax.

Lack of Goals: This option would likely have goals to strive for as part of its framework.

Unclear Requirements, Policies and Authorities: Requires new legislation that may be difficult to enact. Legislation would be needed to provide the authority for a state program and could result in clearer government regulatory roles and responsibilities, clearer requirements, and a more uniform approach to home-generated pharmaceutical wastes.

Environmental Impacts: Less home-generated pharmaceutical waste would enter the environment. This option would not provide an incentive to redesign pharmaceuticals to reduce their environmental impact.

PARTING COMMENTS

The options above serve as starting points for further discussion and information gathering. It should be noted that some of the options may be combined.

The options presented above would allow multiple collection systems to co-exist, which may be necessary because CalRecycle has not found a single preferred collection system for all regions. Each system (continuous collection programs, collection events, and mail-back) has its merits when one considers programs budgets, available collection infrastructure, changing laws and regulations, and local public acceptance. Additionally, regardless of which option is implemented, much work lies ahead in finding solutions to financing, establishing clear goals, state agency responsibilities, and educating the public to meet the ultimate goal of providing safe and secure collection and management of home-generated pharmaceuticals.

‡‡‡‡‡ For example, California's electronic waste (e-waste) program requires approximately 75 staff across state government. Among the 20 or more e-waste programs in the country, California is the only state using an ADF approach. In part, that is because it was the first program, but since then other states have opted for a product stewardship approach, which requires fewer government resources.

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Appendix A. Criteria and Procedures for Model Home-Generated Pharmaceutical Waste Collection and Disposal Programs

Senate Bill 966 (Simitian, Chapter 542, Statutes of 2007) requires the California Integrated Waste Management Board (CIWMB now CalRecycle) to develop model programs for the collection from consumers and proper disposal of unused or expired home-generated pharmaceuticals[1]. In developing model programs in California, the CIWMB is also required to evaluate programs used by other state, local, and other governmental entities. The CIWMB provided a survey to those entities that have collection programs and requested that they complete and return it to the CIWMB. The purpose of the survey was to acquire information on existing home-generated pharmaceutical waste collection programs in California. From the survey results, the Procedures for Model Home-Generated Pharmaceutical Waste Collection and Disposal Programs (Procedures) were developed that would help organizations or local governments create programs through which the public may return unused or expired home-generated pharmaceutical waste (typically a prescription drug dispensed to a consumer, or a non-prescription item, such as over the counter drugs, that are no longer wanted or needed by the consumer) and meet the following minimum criteria and goals of SB 966 and of the Pharmaceutical Working Group (staff from CIWMB, California Department of Public Health (CDPH), Board of Pharmacy, Department of Toxic Substances Control, and the State Water Resources Control Board).

The minimum criteria of SB 966 and of the Pharmaceutical Working Group for home-generated pharmaceutical waste collection model programs are as follows:

1. Requires, at no additional cost to the consumer, the safe and environmentally sound take back and disposal of unused or expired home-generated pharmaceuticals;
2. Ensures protection of the public's health and safety and the environment;
3. Ensures protection of the health and safety of consumers, and employees;
4. Report to the Board the amounts of home-generated pharmaceutical waste collected for purposes of program evaluation for safety, efficiency, effectiveness and funding sustainability, and incidents of diversion of drugs for use or sale;
5. Protects against the potential for the diversion of drug waste for unlawful use or sale;
6. Provides notices and informational materials about potential impacts of improper disposal of pharmaceutical waste and options for proper disposal;
7. Subjects persons or businesses to consequences for failure to comply with model programs per SB 966 and related state and federal pharmaceutical and waste management statutes at the point of transportation, deposition, and consolidation;
8. Requires that once home-generated pharmaceutical waste has been consolidated at a facility or place of business, the waste must be managed as medical or hazardous waste. This would include all statutory requirements for storage and handling as medical or hazardous waste, the use of registered medical or hazardous waste haulers and approved treatment technology for disposal; and
9. Requires collection locations to have written policies and procedures to document their operations and compliance with this home-generated pharmaceutical waste collection program.

Additional goals of SB 966 and the Pharmaceutical Working Group include:

1. Providing for the collection of home-generated pharmaceuticals that is convenient for consumers;

1 Throughout this document, the terms "home-generated pharmaceuticals" or "home-generated pharmaceutical waste" are used. Although the term does not appear in the law establishing this program, it is the term commonly used by stakeholders to refer to unused or expired pharmaceuticals in the possession of consumers.

2. Maintaining privacy of all participants;
3. Preventing the illegal collection of controlled substances through displaying signage or legally manages them if they are collected;
4. Ensuring that medication information is legible, so that it can be identified in case of a poisoning;
5. Developing a sustainable funding source for collection and disposal of home-generated pharmaceuticals, such as grants, utility funding, or advanced disposal fees placed on home-generated pharmaceuticals and local general funds or via extended producer responsibility funding framework.
6. Striving to develop permanent collection programs rather than one-day events, so they will be more accessible to the public;
7. Providing recommendations for implementation of a statewide program; and
8. Recommending statutory changes to, for example, the Medical Waste Management Act.

The following Procedures have been extracted from both the Pharmaceutical Collection Programs Survey collection program information on the internet, and from the Pharmaceutical Working Group and are recommended for pharmaceutical collection programs. The Procedures are not only a tool to determine if a program meets the minimum criteria of model programs, but also can be used as a model to develop a collection and disposal program for unused/expired home-generated pharmaceuticals. The Procedures are broken down by (I) Permanent Home-Generated Pharmaceutical Waste Collection and Disposal Programs, (II) One-Time or Periodic Events, and (III) Mail Back Programs.

I. Procedures for Model Permanent Home-Generated Pharmaceutical Waste Collection and Disposal Programs

As mentioned in the previous section on goals, it is preferable that permanent home-generated pharmaceutical collection programs be developed to provide the public with consistently accessible and convenient venues to drop off unused or expired home-generated pharmaceuticals. The following procedures are basic steps to implement permanent collection programs at these types of facilities.

1. **Types of Collection Facilities –** Only the following may maintain permanent collection locations for home-generated pharmaceuticals: pharmacies with active unrestricted licenses from the California State Board of Pharmacy, police and sheriff's stations, public/environmental health agencies, physician and other licensed health care prescribers' offices, Household Hazardous Waste (HHW) facilities, and healthcare collection sites. Healthcare collection sites are physical locations licensed or operated by individuals or entities licensed by an agency within the Department of Consumer Affairs (DCA), with these locations electing to collect or take-back home-generated pharmaceutical waste and/or sharps, as applicable. Examples of healthcare collection sites include but are not limited to physicians and surgeons' offices, dentists, veterinary offices and pharmacies. If a DCA licensee has their license revoked, suspended, placed on probation or otherwise limited in any way, it shall not operate a healthcare collection site. If collection is at a police station, law enforcement must agree to and be able to collect the controlled substances and other home-generated pharmaceutical waste.

Participation by any entity is voluntary and must be done in accordance with these provisions in these procedures in order to be considered a model program. Jurisdictions such as the City of Los Angeles, San Mateo County, Ventura County, Santa Cruz County, Marin County, Santa Clara County, and nonprofit groups such as the Teleosis Institute are current examples of entities implementing permanent and ongoing programs utilizing these types of venues.

A list of those facilities that collect home-generated pharmaceutical waste shall be provided to the CIWMB by the governmental entity, organization, or business that is implementing these programs. The list of collection facilities shall include the name, address, contact, and telephone number of the facility collecting and disposing of the home-generated pharmaceutical waste.

2. **Government Agency Authorization –** Any participating entity must determine what permits or approvals are needed for home-generated pharmaceutical waste collection. All relevant agencies and programs must authorize the collection and procedures at the collection location. Some agencies to contact are: local environmental health departments, California Department of Public Health Medical Waste Management Program, local hazardous waste departments, and zoning departments for use permits. As an example, medical waste generator permits are a requirement for collection programs, and are issued by local enforcement agencies, which can be the local environmental health department or the California Department of Public Health. The volume of pharmaceuticals collected will determine if a small quantity generator or large quantity generator permit is required.

3. **Medical/Hazardous Waste Hauler/Disposal Arrangements –** Advanced arrangements shall be made with the medical or hazardous waste hauler on the fee schedule, medical or hazardous waste incineration options, packing of materials, insurance, containers, payment, contract, EPA ID number, pick up schedule, and contact telephone numbers. All home-generated pharmaceutical waste transported to an offsite waste treatment facility shall be transported by a medical waste or hazardous waste transporter that has been issued a registration certificate in accordance with the Medical Waste Management Act. A complete list of approved medical waste transporters can be found on the CDPH webpage at http:www.cdph.ca.gov/certlic/medicalwaste/Documents/MedicalWaste/Haulist.pdf. A medical or hazardous waste transporter transporting medical waste shall have a copy of the transporter's valid hazardous waste transporter registration certificate in the transporter's possession while transporting medical waste. It is the responsibility of the collection site to ensure that all home-generated pharmaceutical waste is appropriately picked up and transported by registered waste haulers. Detailed information about each pickup from a collection site and invoices for these services shall be retained by the collection site for three years.

4. **What Can and Cannot Be Collected**
   a. Home-generated prescription drugs dispensed to a consumer, or a non-prescription item in the possession of a consumer, such as over the counter drugs, vitamins and supplements, and veterinary pharmaceutical waste, may be accepted.

   b. Sharps in containers approved by the local enforcement agency may be accepted at collection sites, but shall not be placed in the same containers as the home-generated pharmaceutical waste.

   c. Medical waste such as human surgery specimens, blood samples, vaccines and serum, trauma scene waste, human surgery specimens, cultures from pathology laboratories, items containing human fluid blood vaccines, and serum shall not be accepted.

d. Controlled Substances - Controlled substances cannot be collected by these programs unless a sworn law enforcement officer is onsite to take custody of, document, and dispose of these controlled substances. Controlled substances are a specific category of prescription drugs and are defined as any substance listed in Sections 11053-11058 of the California Health and Safety Code. Some examples of controlled substances include opiates (morphine and codeine), painkillers, muscle relaxants, depressants and stimulants (amphetamines).

5. **Signage –** Signage must be provided regarding what is acceptable for collection and what is not acceptable (controlled substances, sharps, garbage, etc.), as well as the hours during which collection is permitted. Home-generated pharmaceutical wastes are generally classified as household waste and as such can be commingled in containers with other household waste or hazardous waste. Wastes commingled in this manner must be handled as medical or hazardous waste. If home-generated pharmaceutical wastes are mixed with other medical waste or managed as medical waste, the waste shall be segregated for storage in a separate container or secondary container, and that container shall be labeled with the words "INCINERATION ONLY" or other label approved by the CDPH on the lid and sides, so as to be visible from any lateral direction. A stand alone sign may be provided by the consolidation point (facility) which further describes the container as a waste pharmaceutical consolidation container. This sign shall be located in close proximity to the container to direct consumers to the container location. During periods of non-operation this sign may be removed and the container shall be stored in a secure storage area to prevent theft.

   Signage should include instructions on how to deposit pharmaceuticals into the secured container. Any signage should also advise consumers to remove personal information from the medicine containers but leave information as to the type of medication being deposited.

6. **How Home-Generated Pharmaceuticals Shall Be Collected –** Home-generated pharmaceuticals should be emptied from its original container into the secured container at the collection location. The emptied containers and home-generated pharmaceuticals can then be placed in separate collection bins by the consumer for proper management. Staff of the collection site other than pharmacies may assist consumers in placing home-generated pharmaceuticals in the bins if deemed necessary. The collection location must ensure that the home-generated pharmaceutical licensed waste hauler or handler transports the home-generated pharmaceutical for proper destruction. Collected home-generated pharmaceuticals shall not be resold or reused. No individual or collection site shall purchase or offer to purchase home-generated pharmaceutical waste from consumers, nor shall such returned waste be sold, donated, or provided to anyone other than a registered medical or hazardous waste hauler as specified in these procedures.

   a. <u>Packing Home-Generated Pharmaceutical Waste and Controlled Substances</u> – Collection site staff may assist a consumer in opening a container but should not otherwise assist consumers in placing pharmaceutical waste into the bins. With respect to controlled substances, the law enforcement agency whose officers are onsite have discretion over the exact details regarding the handling of controlled substances.

   b. <u>Storage</u> – In accordance with Board of Pharmacy specifications, collection sites located in pharmacies shall not commingle pharmaceutical waste with expired, recalled or other quarantined drugs. Collected home-generated pharmaceuticals may only be stored in the secure sealed containers or in the custody of law enforcement. Once collected, home-generated pharmaceutical waste may be stored at an onsite location for not longer than 90 days when the container is ready for disposal. In certain circumstances, additional storage time may be obtained with prior written approval from the enforcement agency or the CDPH.

The container shall be emptied at least once per year unless prior written approval from the enforcement agency or the CDPH is obtained.

c. Sharps - Sharps may be accepted only if the location is also approved by the local enforcement agency or CDPH as a sharps consolidation point. Sharps and sharps in containers approved by the local enforcement agency cannot be combined in collection bins with home-generated pharmaceutical waste. If the sharps are not brought in a container approved by the local enforcement agency and the collection site is willing to accept sharps, the consumer must place them in a container approved by the local enforcement agency. Employees should never touch the sharps or assist in this process.

d. Chain of Custody- When the home-generated pharmaceutical waste is collected by the facility, the facility becomes the generator of the pharmaceutical waste, which is medical waste, and is responsible for assuring that storage, removal and transportation of full containers and disposal are in accordance with the Medical Waste Management Act by a licensed medical waste or hazardous waste transporter. Detailed information and invoices about each pick up from a home-generated pharmaceutical collection site shall be retained in a log by the collection site for three years after the life of the collection device. Each collection location must keep a log specific to that collection device. The log must contain (a) the name, address phone number and title of the collection site person authorized for the collection device; (b) the address, phone number and location number where device is located; (c) the date the collection device was installed at the location (d) the dates for every opening of the device and purpose of opening; (e) the names of the two persons that accessed the device (one column for collection site's personnel, and one column for the medical or hazardous waste hauler); (f) the weight of home-generated pharmaceutical waste removed from the device; and (g) additional columns for the final disposition of the drugs, and other security measures implemented to prevent unauthorized removals from the device. The log should indicate the name, address and registration number of the waste hauler taking the drugs.

For controlled substances, the signed inventory must accompany the pharmaceutical waste and must stay with law enforcement in the evidence storage locker and through the point of destruction. Before the home-generated pharmaceutical waste is destroyed, the contents must be checked against the inventory to ensure that there has been no diversion. This is a U.S. Drug Enforcement Agency law.

7. Staffing - The following staff are recommended at collection programs to implement the specified tasks:

a. Pharmacist (at pharmacies) – The pharmacist has the discretion to assist any consumer who brings in home-generated pharmaceutical waste or review each consumer's deposit into the collection bin. The consumer shall deposit the items into the secured locked container. If a pharmacist chooses to assist consumers with the identification of pharmaceuticals, the pharmacist should refer customers with pharmaceuticals that have been identified as controlled substances to an appropriate collection location for those items.

b. Law Enforcement – If a permanent home-generated pharmaceutical waste collection program decides to collect controlled substances, a police officer or other law enforcement officer is required to be present to monitor and collect the controlled substances.

c. Hazardous Waste Company Personnel (for collection at HHW facilities) - Hazardous waste personnel should provide drums/containers for collection of non-controlled substances, seal containers, prepare paperwork, transport non-controlled substances for hazardous waste destruction, remove home-generated pharmaceutical waste, provide tracking paperwork from point of collection through destruction, incinerate non-controlled substances at a licensed hazardous waste incinerator, provide a

certificate of destruction, and provide weight of materials collected. Do not allow home-generated pharmaceutical wastes that are hazardous waste (e.g. chemotherapy drugs) to be stored longer than 90 days at the facility as required for the management of hazardous waste.

d. Medical Prescriber Staff - No physician, dentist, veterinarian or other prescriber or the staff in these offices may accept home-generated pharmaceutical waste directly from consumers. It is the consumer's responsibility to deposit the items into the secured locked container. A prescriber may assist consumers with the identification of drugs.

8. Container Security – It is the responsibility of the entity overseeing the collection location to provide for the security of the collected home-generated pharmaceuticals. The home-generated pharmaceutical waste must be deposited into secured containers to prevent diversion and theft opportunities and not allow staff or the entity overseeing the program from having access to the contents. Containers at permanent locations shall be locked and stored in an area that is either locked or under direct supervision or surveillance. The collection device must be within the physical plant of a pharmacy, prescriber's office, police department, or government agency operating the device so that it can only be accessed during operating hours.

Bins located at pharmacies shall have a two key security system--one in the possession of the collection site's designated responsible person and the other in the possession of the licensed hauler who will pick up the contents for appropriate destruction. Containers may be stored in the following manner: a lockable cage on the container, lockable collection bins or kiosks, or lockable closets. Intermediate storage areas shall be marked with the international biohazardous symbol. These warning signs shall be readily legible from a distance of five feet.

Every collection site that provides for home-generated pharmaceutical waste collection shall keep contracts or ownership information for the collection device used for the program. These documents must be retained for the life of the device plus three years following discontinuation or replacement of the collection device. These records shall be readily retrievable at the request of a government enforcement agency.

Home-generated pharmaceutical waste may not be removed from a collection device and stored in a pharmacy, medical office or any other location. Instead, once the pharmaceuticals are removed by the waste hauler, they must be taken by the hauler. Once a collection device becomes full, no more pharmaceutical waste can be accepted from consumers by the collection site until a waste hauler has removed the pharmaceutical waste, and re-stocked the collection device with an empty container. Any theft of or loss from the collected home-generated pharmaceutical shall be reported within 24 hours to the local police department, CDPH, California State Board of Pharmacy, and other agencies that have authorized the collection program.

9. Essential Equipment and Supplies

a. Pharmacies, Physicians, Veterinarians and Other Prescribers' Offices and Police Stations – The following are examples of the types of equipment and supplies that should be provided: caged, lockable secure containers, lockable kiosks, lockable steel bins, refurbished lockable mail boxes with an internal container. These types of collection containers shall be located near a building entrance or in a lobby that allows people to drop off home-generated pharmaceuticals and not be able to retrieve them, in order to prevent theft. Other supplies include black markers to obscure personal data, signage informing the public about what can and shall not be collected.

b. Permanent HHW Collection Facility Equipment – The following are examples of equipment and supplies typically used at permanent HHW collection facilities: four container types (55 gallon lab packing containers, 30-gal cardboard with plastic liner, a 5-gal plastic container for inhalers, and a 5-gallon plastic container for mercury items), gloves, indelible markers, and sharps container and/or mail back sharps disposal kit.

10. **Budget** – In order to ensure that the program is properly run, a budget estimate should be developed so that the program is free for the public to dispose of unused and unwanted home-generated pharmaceuticals at the point of disposal. In doing so the facility will need to determine who will pay for the collection and disposal of home-generated pharmaceuticals and whether there are sufficient funds to pay for any large increases in rates or in amounts collected.

11. **Education and Advertising -** Collection locations operators shall provide educational materials to the community and to consumers dropping off home-generated pharmaceuticals. Educational materials must include information about the problem of pharmaceutical waste entering waterways and drinking water and accidental poisoning from home-generated pharmaceuticals. Operators shall develop and distribute materials advertising the availability of permanent collection programs. Examples of such advertising could include internet web site ads, newspaper ads, flyers (posted at transfer stations, municipal buildings, and pharmacies), press releases, community cable announcements, utility mailings, multi-lingual flyers distributed in utility bills in participating jurisdictions, movie theater advertisements, advertisements on buses and bus stops, print ads in recycling guides, or English and multi-lingual public service announcements. The advertisements should list who is responsible for operation of the collection location, including the name, address and phone number of the operator.

    Collection location operators shall provide instructions and information for consumers prior to bringing items to the collection location. These instructions should include:

    a. A list of what will and will not be accepted (address at a minimum the following: non-prescription drugs, prescription drugs, controlled substances, sharps, thermometers, medical waste).

    b. Instructions on type of personal information to render illegible and pharmaceutical information to retain for purposes of identification.

12. **Data Collection** - Data shall be kept on the total number of pounds collected, the number of residents utilizing the collection facility, and when possible, the types of materials collected for further study and analysis. Examples of collection forms can be accessed at www.teleosis.org/pdf/Medicine_Return_Form.pdf. Security and confidentiality measures must be taken when retaining this data.

13. **Site Visits to Collection Sites** – For programs developed and overseen by public entities, those public entities shall visit collection locations periodically to help assure that procedures are being adhered to. A collection site shall make its premises available for inspection by government agencies with jurisdiction in this area.

II. Procedures for Model Pharmaceutical Waste Collection and Disposal Programs at Government-Sponsored One Time or Periodic Collection Events

Although permanent collection programs are the preferred method to collect and properly manage home-generated pharmaceuticals, some jurisdictions such as Tuolumne County, Fresno County, City and County of Santa

Cruz, and the City of Watsonville provide One-time or Periodic Collection Events. The following procedures are basic steps to implement One-time events:

1. **Collection Site -** Access to the location must be restricted to only consumers dropping off home-generated pharmaceuticals. The designated operator shall observe consumers dropping off home-generated pharmaceuticals and shall ensure that the home-generated pharmaceuticals wastes are stored in such a manner as to prevent theft. If any theft is observed or suspected, the operator shall contact the appropriate law enforcement agency and the Local Enforcement Agency of CDPH. The collection site should include the following:

    a. Pharmacist (if a one day event is at a facility other than a pharmacy) – It is recommended that a licensed pharmacist in good standing with the California State Board of Pharmacy be present at the event.
    b. Dedicated Collection Area - If the collection site is at an HHW facility and the home-generated pharmaceutical waste is being segregated, the facility must provide room to account for secured storage of pharmaceutical collection containers.
    c. Law Enforcement - Law enforcement may participate in a collection event to provide security for event personnel. This is optional and at the discretion of collection organizers. A law enforcement officer is only required to attend and participate in a collection event only if controlled substances are to be accepted at the event. Per U.S. Drug Enforcement Agency (DEA) law, only a law enforcement officer may accept controlled substances from the consumer. If controlled substances will be accepted, the operator of the event shall ask the law enforcement agency that is providing the officer if the agency has any specific requirements that the event must adhere to. For example, the law enforcement agency may specify the type of packaging that the drugs must be contained in to be accepted into their evidence locker, or if the containers the collection event will provide, are adequate for the law enforcement agency purposes. For controlled substances only, law enforcement must be on site at all times and be able to see the collection and movement of the home-generated pharmaceutical wastes from the public to the collection location. Law enforcement must be able to see the transfer of home-generated pharmaceutical wastes from vehicles to the collection containers. The operator should coordinate with law enforcement to determine the appropriate position for law enforcement to be stationed.

2. **Government Agency Authorization -** Any participating entity must determine what permits or approvals are needed for home-generated pharmaceutical waste collection. All relevant agencies and programs must authorize the collection and procedures at the collection location. Some agencies to contact are: local environmental health departments, California Department of Public Health Medical Waste Management Program, local hazardous waste departments, and zoning departments for use permits. As an example, medical waste generator permits are a requirement for collection programs, and are issued by local enforcement agencies, which can be the local environmental health department or the California Department of Public Health. The volume of pharmaceuticals collected will determine if a small quantity generator or large quantity generator permit is required.

3. **Medical/Hazardous Waste Hauler/Disposal Arrangements -** Advanced arrangements shall be made with the medical or hazardous waste hauler on the fee schedule, medical or hazardous waste incineration options, packing of materials, insurance, containers, payment, contract, EPA ID number, pick up schedule, and contact telephone numbers. All home-generated pharmaceutical waste transported to an offsite waste treatment facility shall be transported by a medical waste or hazardous waste transporter that has been issued a registration certificate in accordance with the Medical Waste Management Act. A complete list of approved medical waste transporters can be found on the CDPH webpage at http:www.cdph.ca.gov/certlic/medicalwaste/Documents/MedicalWaste/Haulist.pdf. A medical or hazardous

waste transporter transporting medical waste shall have a copy of the transporter's valid hazardous waste transporter registration certificate in the transporter's possession while transporting medical waste. It is the responsibility of the collection site to ensure that all home-generated pharmaceutical waste is appropriately picked up and transported by registered waste haulers. Detailed information about each pickup from a collection site and invoices for these services shall be retained by the collection site for three years.

4. What Can and Cannot Be Collected

a. These programs provide for the collection and disposal of home-generated prescription drugs dispensed to a consumer, or a non-prescription item in the possession of a consumer, such as over the counter drugs, vitamins and supplements, and veterinary pharmaceutical waste.

b. Sharps in containers approved by the local enforcement agency may be accepted at collection sites.

c. Medical waste such as human surgery specimens, blood samples, vaccines and serum, trauma scene waste, human surgery specimens, cultures from pathology laboratories, items containing human fluid blood vaccines, and serum shall not be accepted.

d. Controlled Substances - Controlled substances cannot be collected by these programs unless a sworn law enforcement officer is onsite to properly collect, document, and dispose of these controlled substances. Controlled substances are a specific category of prescription drug and are defined as any substance listed in Sections 11053-11058 of the California Health and Safety Code. Some examples of controlled substances include opiates (morphine and codeine), painkillers, muscle relaxants, depressants and stimulants (amphetamines).

5. Signage – Signage must describe what is acceptable for collection and what is not acceptable (controlled substances, sharps, garbage, etc.). Home-generated pharmaceutical wastes are generally classified as household waste and as such can be commingled in containers with other household waste or hazardous waste. Wastes commingled in this manner must be handled as medical or hazardous waste. If home-generated pharmaceutical wastes are mixed with other medical waste or managed as medical waste, the waste shall be segregated for storage in a separate container or secondary container, and that container shall be labeled with the words "INCINERATION ONLY" or other label approved by the CDPH on the lid and sides, so as to be visible from any lateral direction. This sign shall be located in close proximity to the container to direct consumers to container location. During periods of non-operation this sign may be removed and the container shall be stored in a secure intermediate storage area.

Signage should include instructions on how to deposit pharmaceuticals into the secured container. Any signage should also advise consumers to remove personal information from the medicine containers.

6. How Home-Generated Pharmaceuticals Shall Be Collected

Home-generated pharmaceuticals should be emptied from its original container into the secured container at the collection location. The emptied containers and home-generated pharmaceuticals can then be placed in separate collection bins by the consumer for proper management. Staff of the collection site other than pharmacies may assist consumers in depositing home-generated pharmaceuticals in the bins when needed. The collection location must ensure that the medical or hazardous waste hauler or handler transports the home-generated pharmaceutical waste for proper destruction. Collected home-generated pharmaceuticals shall not be resold or reused. No individual or collection site shall purchase or offer to purchase home-generated pharmaceutical waste from consumers, nor shall such returned waste be sold, donated, or provided to anyone other than a registered waste hauler as specified in these procedures.

a. Packing Home-Generated Pharmaceutical Waste and Controlled Substances - Collection site staff may assist a consumer in opening a container but should not otherwise assist consumers in placing pharmaceutical waste into the bins. With respect to controlled substances, the law enforcement agency whose officers are onsite have discretion over the exact details regarding the handling of controlled substances.

b. Storage - Collected home-generated pharmaceuticals may only be stored in the secure sealed containers or in the custody of law enforcement. Once collected, home-generated pharmaceutical waste must be removed the same day from the location in which the one-day or periodic event was held but may be stored at a secure location for not longer than 90 days when the container is ready for disposal. In certain circumstances, additional storage time may be obtained with prior written approval from the enforcement agency or the CDPH. The container shall be emptied at least once per year unless prior written approval from the enforcement agency or the CDPH is obtained.

c. Sharps - Sharps may be accepted only if the location is also approved by the local enforcement agency or CDPH as a sharps consolidation point. Sharps and sharps in containers approved by the local enforcement agency cannot be combined in collection bins with home-generated pharmaceutical waste. If the sharps are not brought in a container approved by the local enforcement agency and the collection site is willing to accept sharps, the consumer must place them in an approved sharps disposal container. Never have employees touch the sharps or assist in this process.

d. Chain of Custody - When the home-generated pharmaceutical waste is collected by the facility, the facility becomes the generator of the pharmaceutical waste, which is medical waste, and is responsible for assuring that storage, removal and transportation of full containers and disposal are in accordance with the Medical Waste Management Act by a licensed medical waste or hazardous waste transporter. Detailed information and invoices about each pick up from a home-generated pharmaceutical collection site shall be retained in a log by the collection site for three years after the life of the collection device. Each collection location must keep a log specific to that collection device. The log must contain (a) the name, address phone number and title of the collection site person authorized for the collection device; (b) the address, phone number and location number where device is located; (c) the date the collection device was installed at the location (d) the dates for every opening of the device and purpose of opening; (e) the names of the two persons that accessed the device (one column for collection site's personnel, and one column for the medical or hazardous waste hauler); (f) the weight of home-generated pharmaceutical waste removed from the device; and (g) additional columns for the final disposition of the drugs, and other security measures implemented to prevent unauthorized removals from the device. The log should indicate the name, address and registration number of the waste hauler taking the drugs.

   For controlled substances, the signed inventory must accompany the pharmaceutical waste and must stay with law enforcement in the evidence storage locker and through the point of destruction. Before the home-generated pharmaceutical waste is destroyed, the contents must be checked against the inventory to ensure that there has been no diversion. This is a U.S. Drug Enforcement Agency law.

7. Staffing

Event organizers are encouraged to have the following staff at collection sites to implement the specified tasks:

a. Greeter - direct people to the collection location and answer questions. Greeters can also screen incoming people and wastes for problems. If the event is large enough, radios are useful.

b. Law Enforcement Staff - to provide security, take possession of controlled substances if it has been determined that a controlled substance has been brought in by a consumer, transport controlled substances to evidence storage locker, document the collection of controlled substances, and arrange for and ensure U.S. DEA authorized witnessed destruction of controlled substances. Law enforcement staff can also provide crowd control and watch for problem people. A law enforcement officer is required to attend and participate in a collection event only if controlled substances are to be accepted at the event. Only a law enforcement officer may accept controlled substances, not collection event personnel. If controlled substances will be accepted, confirm with the law enforcement agency providing an officer for the event, whether they have requirements for the type of packaging the drugs must be contained in to be accepted into their evidence locker, or if containers the collection event will provide are adequate for the law enforcement agency purposes. Law enforcement may participate in a collection event to provide security for event personnel. This is optional at the discretion of collection organizers and not required for all events.

c. Pharmacist - to determine if a medication is a controlled substance, identify non-labeled home-generated pharmaceutical waste, inventory controlled substances (if applicable), witness, and sign the inventory.

d. Hazardous Waste Personnel - Provide drums/containers for collection of non-controlled substances. Seal containers, prepare paperwork, transport non-controlled substances for hazardous waste destruction, remove pharmaceutical waste on the same day as the event, provide tracking paperwork from point of collection through destruction, incinerate non-controlled substances in licensed hazardous waste incinerator, provide certificate of destruction, provide weight of materials collected, and complete data entry.

8. **Container Security –** It is the responsibility of the entity overseeing the collection event to provide for the security of the collected home-generated pharmaceuticals. The home-generated pharmaceutical waste must be deposited into secured containers to prevent diversion and theft opportunities and not allow staff or the entity overseeing the event from having access to the contents. The collection device must be within the physical plant of a pharmacy, prescriber's office, police department, or government agency operating the device so that it can only be accessed during operating hours.

   Every collection event that provides for home-generated pharmaceutical waste collection shall keep contracts or ownership information for the collection device used for the program. These documents must be retained for the life of the device plus three years following discontinuation or replacement of the collection device. These records shall be readily retrievable at the request of a government enforcement agency.

   Home-generated pharmaceutical waste may not be removed from a collection device and stored in a pharmacy, medical office or any other location. Instead, once the pharmaceuticals are removed by the waste hauler, they must be taken by the hauler. Once a collection device becomes full, no more pharmaceutical waste can be accepted from consumers by the collection site until a waste hauler has removed the pharmaceutical waste, and re-stocked the collection device with an empty container. Any theft of or loss from the collected home-generated pharmaceutical shall be reported with 24 hours to the local police department, CDPH, California State Board of Pharmacy, and other agencies that have authorized the collection program.

9. **Recommended Equipment and Supplies**
    a. Tools for counting home-generated pharmaceutical waste (pharmacist should provide this);
    b. Hazardous waste containers;
    c. Gloves (Disposable latex or non-latex);
    d. Sealable plastic bags (One-gallon and snack size, with external slide mechanism);
    e. Extension cords, grounded;
    f. Survey forms (examples can be found at www.teleosis.org/pdf/Medicine_Return_Form.pdf);
    g. Indelible markers;
    h. Packing tape;
    i. Containers- Check with your contracted medical or hazardous waste hauler for appropriate containers;
    j. Sharps disposal container - Provide sharps containers approved by the local enforcement agency to collect sharps if the location is also approved by the local enforcement agency or CDPH as a sharps consolidation point; and.
    k. Personal protective equipment – All staff must wear gloves (latex or non-latex) at all times when handling pharmaceutical waste. This is important as the containers may be powdery, sticky, and dirty. Accidental ingestion (even through skin or breathing) must be avoided. The use of facemasks should be considered, especially for the pharmacist who may be conducting the physical examination of the home-generated pharmaceutical waste.

10. **Budget -** An estimate of the budget should be developed and the program must be free to the public to dispose of unused and unwanted home-generated pharmaceuticals.

11. **Education and Advertising** – Collection event operators shall provide educational materials to the community and to consumers dropping off home-generated pharmaceuticals. These materials must include information about the problem of pharmaceutical waste entering waterways and drinking water and accidental poisoning from home-generated pharmaceutical waste. Event operators shall develop and distribute materials advertising for the collection event. Examples of such advertising could include internet web site ads, newspaper ads, flyers (posted at transfer stations, municipal buildings, and pharmacies), press releases, community cable announcements, utility mailings, multi-lingual flyers distributed in utility bills in participating cities, movie theatre advertisements, advertisements on buses and at bus stops, print ads in recycling guides or English and multi-lingual public service announcements. The advertisements should list who is responsible for operation of the collection location, including the name, address and phone number of the operator.

    Collection event operators shall provide instructions and information for consumers to use as they prepare to bring items to the collection event:

    a. Date, Time, Location, operating hours, and contact information for the collection event.
    b. A list of what will and will not be accepted (address at a minimum the following: non-prescription drugs, prescription drugs, controlled substances, sharps, thermometers, medical waste).
    c. Instructions on type of personal information to render illegible and pharmaceutical information to retain for purposes of identification.

12. **Data Collection** - Determine amounts of home-generated pharmaceuticals collected along with the number of donators. If time allows, determine the types and amounts of home-generated pharmaceuticals collected. This information could be used for further studies and policy recommendations. Security and confidentiality measures should be taken when retaining this data.

Each collection event must have a log specific to that collection event. The log must contain (a) the name, address phone number and title of the collection site person authorized for the collection event (b) the address, phone number and location number where the event was located; (c) the date the collection event took place; (d) the names of at least one person from the event who witnessed the pickup by the licensed waste hauler (e) the name of the waste hauler's staff person who picked up the collected waste; (f) the weight of home-generated pharmaceutical waste removed from collection event; and (g) additional columns for the final disposition of the drugs, and other security measures implemented to prevent unauthorized removals. The log should indicate the name, address and hauler number of waste hauler taking the drugs. These records shall be kept for 3 years after the life of the collection event by the host agency.

13. **Site Visits to Collection Sites** – The event organizer shall inspect the location to ensure compliance with all requirements. The CIWMB may request a report summarizing the activities of each collection location including amounts of home-generated pharmaceutical waste collected and the number of days in operation as a collection location for home-generated pharmaceuticals.

III. Procedures for Model Pharmaceutical Waste Collection and Disposal Programs Through a Mail Back Program

In some jurisdictions mailing back used and unused home-generated pharmaceuticals may be the only or most convenient option for the proper management of these items. An example is the State of Maine, which uses pre-paid mailing envelopes available at pharmacies, doctors' offices, and post offices to collect home-generated pharmaceuticals that may include controlled substances. In addition, some pharmaceutical companies, such as Celgene, will take back their own home-generated pharmaceuticals via mail. Celgene allows patients to return unused drugs such as thalidomide purchased from the company, via UPS at no shipping cost to the patient. The following are some guidelines to look at when undertaking such a program:

Locations for Mail-Back Programs shall only be allowed if the following requirements are met:

1. Each entity overseeing either a Mail-Back Location or Mail-Back Program shall ensure that the home-generated pharmaceutical waste is destroyed in accordance with applicable regulations. CIWMB may request that each Mail-Back Location or Program provide information on the amounts of home-generated pharmaceuticals received and destroyed.

2. Determine locations where home-generated pharmaceuticals can be mailed for proper management and destruction. These facilities must be DEA-approved and able to accept controlled substances for destruction if controlled substances are mailed directly to the facility. In addition, these facilities must be able to provide data on the amounts of home-generated pharmaceuticals received and destroyed.

3. Operators of mail-back programs shall obtain self-sealing pre-addressed and pre-stamped envelopes that are approved by the U.S. Postal Service for containment and transportation of home-generated pharmaceutical waste. The envelopes shall also include an instruction sheet on how to package and send the home-generated pharmaceuticals.

4. Operators of mail back programs may provide postage-paid envelopes to pharmacies, one-time collection events, hospice care providers, doctors' offices, and post offices to be utilized by consumers for the mailing and destruction of unused and expired home-generated pharmaceuticals.

5. Envelopes shall be tracked to assure that all envelopes are used for their intended purposes and that all of the home-generated pharmaceuticals get to the destruction facility.

6. Operators may advertise its mail back program at pharmacies, convalescent homes, and retirement homes in order to inform potential users of the program of its availability and requirements for participation.

7. The operator shall review data on the amounts of home-generated pharmaceuticals collected to assure that the amounts are increasing and shall make changes to the program as needed to the program to assure continued growth.

Appendix I-Definitions

1. **Controlled Substance**-any substance listed in Chapter 2 (commencing with Section 11053) of Davison 10 of the CA Health & Safety Code.

2. **Event –** Include programs and one- time events for the collection of home-generated pharmaceutical waste to assure appropriate disposal of these items.

3. **Collection Programs** – include permanent collection programs, temporary collection programs, and mail back collection programs

4. **Model Program** - CIWMB a[p[proved program through which the public may return unused or expired home-generated that meets statutory criteria.

5. **Over the Counter Drug** - a non-prescription drug a defined per CA Business & Professions Code Section 4025.1 which states "non-prescription drugs" means a drug which may be sold without a prescription and which is labeled for use by the consumer in accordance with the laws and rules of this state and the federal government.

6. **Collection Facility** - any entity CIWMB finds appropriate to implement or evaluate a model home-generated pharmaceutical waste program. The participant must agree to participate as a model program. Entities that may qualify to participate:

   a. Governmental entities (includes police and sheriff's stations, public/environmental health agencies and HHW facilities);
   b. Pharmacies with active unrestricted licenses from the California State Board of Pharmacy;
   c. Other Physician and other licensed health care prescribers' offices; and
   d. Healthcare Collection Sites that are licensed by the Department of Consumer Affairs

7. **Pharmaceutical Waste** - In this document it is considered to be a prescription drug dispensed to a consumer or a non-prescription item, no longer wanted or need by the consumer and includes home-generated pharmaceuticals in many delivery systems, such as pills, liquids, and inhalers.

8. **Prescription Drug** - is a dangerous drug as defined per California Business and Professions Code Section 4022 which means any drug unsafe for self-use in humans or animals, without the oversight of a licensed prescriber and includes the following:

   a. any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription, "Rx only", or words of similar import.
   b. any other drug that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to CA Business & Professions Code Section 4006.

Appendix B. Overview of Pharmaceutical Collection Programs Outside of California

International Programs	Canada: Alberta*	Canada: British Columbia*	Canada: Nova Scotia*	Canada: Saskat-chewan*	Return Unwanted Medicines (RUM) Project	France : Cyclamed Program	Portugal: Valormed Program	Integrated Waste MaNAgement System (SIGRE)	Sweden: Apoteket AB Environmental Program
Sources	1	1, 13	1	1	1	1	1	1, 12	1
Type of Funding	Mainly Industry & small provincial gov't grants	Industy	Industy	Community Pharmacies	Mainly Federal Gov't (with some Industry)	Industry, pharmacies, wholesalers	Pharmaceutical companies pay an eco-fee of 0.00504 Euro for each package placed in market	Pharmaceu-tical industry based on vol. of sales	Federal government. Apoteket is a national retail pharmacy. Also takes meds from hospitals, vets, dentists, etc.
Start date	1988	1996	Mid 90s	1997	1999	1993	2001	2003	1970
Population (2006)*	3,300,000	4,300,000	930,000	990,000	20,000,000	63,000,000	10,600,000	45,200,000	9,100,000
Collection point	Pharmacies	Pharmacies	Pharmacies	Pharmacies	Pharmacies	Pharmacies	Pharmacies	Pharmacies	Pharmacies
Stewardship Organizations		Pharmaceutical Stewardship Association (PCPSA) is a non-profit						SIGRE is a non-profit stewardship org	
Total program cost (US $, 2006)	NA	$333,606	$34,808	NA	$1,144,802	$3,878,534	NA	NA	$1,149,775
Cost($)/capita (preliminary estimate)	NA	$0.08	$0.04	NA	$0.06	$0.06	NA	NA	$0.13
Cost ($)/unit collected	NA	$0.006/pill	$.001/pill	NA	NA	0.4 euros/ kilo	NA	NA	1.6 eruo/ kilo
EOL materials management (% of total program cost)	NA	NA	NA	NA	NA	63%	NA	NA	NA

Environmental									
Did collection include primary packaging?		no						yes	
Product collected (metric tonnes)	37	35.7	$	16.4	NA	13,169	694	2,624	1019
Percent collected (from available for collection)	NA	NA	NA	NA	NA	80%	NA	NA	65-75%
Program effectiveness									
Pharmacy Participation (Total #)	900	942	259	350	5000	22,500	2,786	20,406	980
Pharmacy Participation (Percent)	100	95	100	90	100	85	98.5	100	100
Collection Per Capita (kilograms/capita)	0.01	0.008	0.01	0.02	0.017	0.21 (0.09 w/o pkg)	0.054	0.058	0.1
Public awareness/participation	NA	NA	NA	NA	60%	77%	NA	NA	43%

* Other Canadian provinces have programs, these four were selected for their performance with one of the following factors: high collection, high collection/capita, or low cost.

Appendix B. Overview of Pharmaceutical Collection Programs Outside of California

State Programs	Colorado: Pilot	Iowa: Pilot	Maine: pilot	Washington State: Pilot
Sources	3, 8,9	3, 5, 7	2, 3	3, 4, 5, 10, 11
Type of Funding	USEPA leases 10 collection boxes; State grants (public health and pollution prevention) $27,000, Local water agency	State grants to participating pharmacies (funded by grant) or consumers purchase mail back envelopes	USEPA grant for mail back program	Public and Private Sectors (variety of federal, state and local govt entities, health coop, and pharmacy chain)
Start date	2009	2009	2007	2006
Population (2006)*	4,751,474	2,967,270	1,313,355	6,360,529
Collection Point	Pharmacies & local health agencies	Pharmacies or mail back	Mail Back	Pharmacies
Total program cost (US $, 2006), except as noted	Unclear. Variety of sources. Some amounts not specified.	$165,000 (over 3 years)	$150,000 (over 2 years)	NA
Cost($)/capita	NA	NA	NA	NA
Cost ($)/unit sold				$0.01 to $0.02 per container
Cost ($)/unit collected	NA	NA	$18.79/mailer (actual & in-kind costs phase I and II), $7.50 /mailer phase III (longer term), ave. weight of mailer 7 ounces	NA
Environmental				
Product (with its packaging)	NA	NA	1.15 tons	5 tons
Percent collected (from available for collection)	NA	NA	NA	NA
Program effectiveness				
Pharmacy Participation (Total #)	NA	NA	NA	54 MWR facilities, 1,300 pharmacies
Pharmacy Participation (Percent)	NA	NA	NA	NA
Collection Per Capita (kilograms/capita)	NA	NA	NA	NA
Public awareness/participation	NA	NA	NA	NA

Appendix B. Overview of Pharmaceutical Collection Programs Outside of California

Sources	Type of Resource	Date	Weblink
1. Health Canada Environmental Impact Initiative	Report	November 1, 2009	http://www.enviroadvisory.com/pdf/Takeback.pdf
2. EPA website	Executive Summary to ME report	April 1, 2010	http://www.epa.gov/aging/RX-report-Exe-Sum/
	Access to full ME report	April 1, 2010	http://www.surveymonkey.com/s/HSGKBDD
3. US census	Database	2006	http://www.census.gov/popest/states/tables/NST-EST2008-01.xls
4. Snohomish County Solid Waste Management Division	Presentation	June 30, 1905	http://www.productstewardship.us/associations/6596/files/Sego_Jackson_presentation2.ppt
5. Oregon Pharmaceutical Take Back Stakeholder Group	Report	July 1, 2007	http://www.oracwa.org/downloads/drugtakeback-rpt_0907.pdf
6. Iowa Pharmacy Association	Frequently Asked Questions	2007	http://www.iarx.org/TakeAway/Default.aspx#FAQ
7. Souix City Journal	Newspaper Article	February 1, 2010	http://www.siouxcityjourNAl.com/news/local/article_1fe2192e-93cf-5308-ae24-d1d4ce4b25a0.html
8. Colorado Department of Public Health and Environment	Press Release	2009	http://www.cdphe.state.co.us/release/2009/121009.html
9. Colorado Department of Public Health and Environment	Presentation	October 2, 2009	http://www.cehaweb.com/documents/MedicationTake-BackPilotProjectCEHAPowerpoint.ppt
10. Northern Light	Newspaper Article	May 24, 2010	http://www.cehaweb.com/documents/MedicationTake-BackPilotProjectCEHAPowerpoint.ppt
11. Progress Report for Pharmaceuticals from Households: A Return Mechanism (PH:ARM)	Fact Sheet	April 1, 2008	http://www.productstewardship.us/associations/6596/files/PHARMProgressReport2Apr2008.pdf
12. Farmaindustria in 2007 (Spain), Integrated Packaging Management and Collectino System (SIGRE)	Report	2007	http://www.farmaindustria.es/idc/groups/public/documents/publicaciones/farma_094905.pdf
13. British Columbia, Canada (access to stewardship plan and annual reports)	Webpage	Jul-10	http://www.medicationsreturn.ca/british_columbia_en.php
14. Communications with Jeff Rayner, Stewardship Ontario,	Conversation and email	9-Sep-10	

California State Board of Pharmacy
1625 N. Market Blvd, Suite N 219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

August 13, 2010

Burke Lucy
CalRecycle
801 K Street
Sacramento, CA 95814

Sent via email to: Burke.Lucy@calrecycle.ca.gov

RE: Comments on Evaluation of Home-Generated Pharmaceutical Programs in California

Dear Burke,

Thank you for this opportunity to provide comments on the above draft report to the Legislature that was issued in July by CalRecycle.

Your 2010 draft report focuses on three categories of assessment for drug take-back programs:

- An evaluation of the model programs for efficacy, safety, statewide accessibility and cost effectiveness,
- Consideration of the incidence of diversion of drugs for unlawful sale and use, and
- Recommendations for the potential implementation of a statewide program and statutory changes.

Our comments will address these categories.

The board strongly supports the development of appropriate drug-take back programs to meet an ever growing demand by the public to dispose of their unwanted pharmaceuticals in ways other than flushing them down the drain or placing them in trash receptacles. Over the last two years, the board has worked closely with CalRecycle (then the Integrated Waste Management Board) and the Department of Public Health in developing Model Guidelines for pharmacies and others that operate occasional or ongoing drug take-back programs.

These guidelines, adopted by the California Integrated Waste Management Board in February 2009, were promoted to California pharmacies in the February 2010 board newsletter to its licensees. However, due to budget and staffing issues in mid-2009, what would have been the August 2009 newsletter became the February 2010 newsletter, which was the next published newsletter of the board. As such, it is important to note

that pharmacies were not officially advised of the board's recommendations for use of the model guidelines until March 2010.

Thus, data collected from pharmacies operating take-back programs in 2010 or earlier are not likely to include data from model programs operating in pharmacies. Many pharmacies declined to establish take back programs at all until they knew the board's policy on such programs. Instead, only a limited number of pharmacies operated take back programs, none of which the board is aware of complied with the model guidelines.

At the current time, the board has just begun to add compliance checks of drug take-back programs in pharmacies during board inspections. The prevalence of such programs and the degree of adherence to the model take-back program requirements has not been assessed. However, board inspectors are advising any collection program operated in a pharmacy to comply with the guidelines.

Consequently and unfortunately, data reported from drug take back programs in California does not represent the impact of the model guidelines on collection possible through drug take-back programs in pharmacies.

From the Board of Pharmacy's perspective, the danger of drug take-back programs is one of creating drug diversion opportunities. Prescription drugs have value when they are no longer wanted by the consumer. This is a problem when they are left in the home and not disposed of, as well as when disposed of in a take-back program. Thus any take-back program needs to ensure it has appropriate safeguards against drug diversion by pharmacy staff, collection staff, and by the public.

In the last two years, the board has identified the diversion issues from non-model guideline take-back programs. Here are some examples:

1. Several months ago, a Northern California coroner's office advised the board of the death of a young woman who died from a drug overdose. An inspection of the woman's home identified a number of pills in baggies, and multiple prescription containers with diverse patient and pharmacy names on them. The woman worked as an esthetician outside a pharmacy, and near where an unattended large take-back drug collection bin was located. On the collection bin were directions to empty drugs from a prescription vial into a baggie before placing the drugs in the bin. The coroner believed that this was the likely source of this woman's drugs and reported this situation to the board. The board has contacted one individual whose name was on one prescription vial found in the home, and the patient stated she had given her drugs to someone in the pharmacy to place in the take-back bin. This take-back bin did not conform to California's model guidelines. The board also notes that once it began its investigation, the pharmacy discontinued the collection program.
2. In November 2008, a pharmacist in Washington pleaded guilty to collecting expired and unexpired medication from medical providers, hospices and clinics purportedly to redistribute for humanitarian relief. However, he was instead filling

the pharmacy's stock bottles with these drugs for re-dispensing the drugs to unknowing patients of the pharmacy (Attachment 1).

3. The board disciplined two unrelated pharmacies in 2009 for different schemes involving kick backs from reverse distributors for falsely claiming to return drugs to the manufacturer to obtain a rebate for returned drugs that the pharmacies had not really purchased but instead obtained from a reverse distributor (Attachment 2).
4. A photograph of an inappropriate collection activity where a large fishbowl is placed on a pharmacy's cashier counter that creates diversion opportunities by making returned drugs accessible to the public (Attachment 3).
5. A photograph displaying the need for security of the collected bins given the diversity and volume of items collected (Attachment 4).
6. A 2009 newspaper article about a police officer accused of stealing prescription pain medicine from the family of a man who had recently died. According to the report, the officer had advised the family that the police department offered a disposal service for prescription medicine (Attachment 5).

The board notes that is extraordinarily difficult to catch pharmacies that collect or purchase drugs from any unapproved source (such as drug take back, drug samples, physicians) and place them in pharmacy stock containers. The examples above are rarities in that they were detected.

Simply put, drug take-back programs operating where the pharmacy or patients can access the surrendered drugs, creates serious problems.

California has enacted the nation's toughest control measures to preserve the integrity of the state's prescription drug supply. This was in response to drug diversion and counterfeit drugs identified the nation's and California's drug supply. Over a staggered implementation schedule from 2015-2017, prescription drugs dispensed in California must be accompanied by an electronic pedigree that originates with the manufacturer identifying any entity that has owned the drugs as they are transferred through the pharmaceutical supply chain from manufacturer to wholesaler(s) to pharmacy. This e-pedigree system will ensure that drugs located in a pharmacy can be traced to their origins via electronic coding on the prescription stock bottle. However, despite the complexity of the e-pedigree system with respect to the statutory requirements and the accompanying technology to comply (which necessitated the far-off future implementation schedule), the value of the e-pedigree system could be lessened if pharmacy staff can access drugs from non-model take-back programs and re-add these drugs to stock containers. This would be a significant loss to the prescription drug supply and to patients in California.

Returning to the report, the board specifically agrees with the statement (page 24):

> Certain requirements in the Guidelines presented unique challenges to some programs. As discussed above safety (security) issues are usually the primary reason why existing programs did not qualify as model programs. Meeting these safety issues often involve increased costs.

However, it is these security features that provide the appropriate safety necessary to guard against drug diversion. Drug diversion by patients and licensed entities is a significant problem and the state needs to ensure that its drug take-back programs do not create more venues for diversion. Thus the costs of such security measures are necessary for those entities desiring to operate drug take-back programs.

The board strongly believes that the CIWMB/CalRecycle model guidelines need to be enacted so that they can be more effectively enforced. Enactment will increase compliance with appropriate disposal and end the current confusion about how to operate a take-back program statewide.

The board also notes that mail return by patients of unwanted drugs may offer additional advantages that are not greatly emphasized in the guidelines. This option warrants further review and discussion.

And as stated earlier, California pharmacies' adherence to these model programs has really not yet occurred as few pharmacies have modeled their programs on the guidelines in the few months since the board's policy position was published. Enactment of the standards, where participation by the pharmacy is voluntary, would likely increase participation.

The board anticipates working with interested stakeholders to enact the model guidelines and ensure the safety of the state's prescription drug supply and yet allow patients to appropriately dispose of their unwanted drugs.

Please do not hesitate to contact either me or the board's executive officer, Virginia Herold, with questions.

Sincerely,

STAN WEISSER
President

attachments

Attachment 12

EDMUND G. BROWN JR.
Attorney General

State of California
DEPARTMENT OF JUSTICE

BUREAU OF NARCOTIC ENFORCEMENT
P.O. BOX 161089
SACRAMENTO, CA.95816-1089
Telephone: 319-9062
Fax: 319-9448

December 9, 2010

Re: **New Data Collection Vendor for California CURES' Prescription Monitoring**

Dear: Pharmacy/Dispensing Prescriber/Clinic or Software Vendor

This letter is to advise you and/or your vendor of changes to CURES in regards to:

- Prescription Data Submissions to CURES effective January 1, 2011.
- Why the change in vendor
- ASAP format change from ASAP 2005 to ASAP 2009
- Data Submission and Validation process
- Data Errors
- File Errors
- File Types and File Naming Conversation
- First Year Medical Resident Drug Enforcement Administration (DEA) Number Suffix; and
- Optional Data Fields
- Paper submission limitations
- Requests for CURES Data Deletion/Correction;
- Special Characters Appearing in the Data Fields.
- Zero fill

Prescription Data Submissions to CURES Effective January 1, 2011

The Department of Justice (DOJ) awarded the contract for the collection of controlled substance prescription data as defined in Health & Safety Code section 11165 to Atlantic Associates, Inc. (AAI) effective January 1, 2011.

With the DOJ's direction and approval, AAI is incorporating several new and essential features in their data collection process which will provide significant benefits to the Pharmacies, Physicians and the Bureau of Narcotic Enforcement (BNE). These changes will be implemented with the intention of improving the current data submission and enforcement process. I will also attempt to provide you with some clarity and direction.

The reason for the late notice regarding this change in vendors was due to the State of California budget impasse. Because there was no budget, the contract could not be awarded, the contract documents approved, or work started by AAI until the State of California had an approved and signed budget in place.

Why a Change of Vendor?

The State of California adheres to a competitive bid process when awarding contracts for services that state employees/departments are unable fulfill. The current vendor, Infinite Solutions, Inc. (ISI) had the controlled substance prescription data collection contract for the past two years; however, as mentioned, due to the State of California's competitive bid process a new vendor was awarded this contract effective January 1, 2011. The competitive bid process is the right of all taxpayers. As such, the DOJ conducted a comprehensive, competitive, and fair evaluation in our selection of this vendor. Many of you may remember this vendor as the vendor DOJ utilized prior to ISI.

The new contract with AAI is effective for three years with an option to renew an additional two years.

ASAP 2009 Version 4.1 Data Format

All controlled substance prescription data needs to be submitted in the American Society for Automation in Pharmacy (ASAP) standards, ASAP 2009 version 4.1 format. All pharmacies and dispensing Prescriber/Clinic must submit their controlled substance prescription data electronically in the ASAP 2009 version 4.1 format. **All other format submissions will be rejected.**

AAI will accept controlled substance prescription data in ASAP 2009 Version 4.1 format per the DOJ's mandate; however, until **July 1, 2011**, AAI will continue to accept controlled substance prescription data in ASAP 2005 Version 3.0 format

Like several agencies, the DOJ is moving towards electronic solutions and highly encourage the submission of controlled substance prescription data in electronic formats. Several ways of accepting electronic data has been/are being incorporated by the new vendor to facilitate the submission of electronic data. Further information regarding these processes will be forthcoming.

Data Submission and Validation process

The DOJ has provided AAI with a set of requirements for validating the controlled substance prescription data submitted by individual pharmacies and dispensing prescriber/clinic. AAI will perform the validations and accept only files that meet the established criteria and reject files that do not meet this criteria. AAI will also be notifying pharmacies when controlled substance prescription data has been validated and accepted or rejected.

Errors

The California Business and Professional (B&P) Code and California Health and Safety (H&S) Code 11165 (d) requires pharmacies and H&S Code 11190 requires dispensing prescriber/clinics to submit specific data such as name of patient, gender, date of birth, and prescription details, etc. The ASAP 2009 Version 4.1 format has many mandatory and optional data fields. Missing mandatory field data will create an error message during the validation process.

Record Errors identified during the validation process will result in the rejection of the erred records. When a Record Error notification is received by the pharmacy, AAI will ask the Pharmacy/Dispensing Prescriber/Clinic or Software Vendor to resubmit the original record with 02 (void) in DSP01 field and submit the corrected record with 01 (revise) in DSP01 field. This will overwrite the original record submitted. If the record was sent in error or the customer never picked up, it should be resubmitted with '02' (void) in the DSP01 field and the record will be removed. **This will only occur if the file was submitted in the ASAP 2009 Version 4.1 format**.

File Errors identified during the validation process will result in the rejection of the entire file. When a File Error notification is received by the pharmacy, the pharmacy will resubmit the entire file again with the corrected data.

File Types and File Naming Convention

AAI will accept controlled substance prescription data in ASAP 2009 Version 4.1 format per the DOJ's mandate; however, until **July 1, 2011**, AAI will continue to accept controlled substance prescription data in ASAP 2005 Version 3.0 format. Data must be submitted in a .DAT or a .TXT format. Adhering to the file naming convention and the ASAP 2009 Version 4.1 format specification standards will eliminate most of the data rejection errors.

Medical Resident DEA Number Suffix:

In order to capture all controlled substance prescriptions, as required by the California Health and Safety Code and the Business and Professionals Code, the following is being instituted as it relates to Medical Residents. When reporting prescriptions for residents, the institution's or supervising physician's (if outside the hospital environment) DEA number will be used along with a DEA number suffix assigned by the institution to the individual medical resident. The formatting of this process is as follows:

1. The Prescriber Information Segment, **PRE02**, is used to identify the institution's or supervising physician's (if outside the hospital environment) DEA number.

2. The Prescriber Information Segment, **PRE03**, will be used to enter the identifying suffix for the medical resident as assigned by the institution. This field will allow up to seven (7) characters to identify an individual medical resident.

Optional Fields

In addition, the DOJ requests that optional data fields identified within ASAP continued to be submitted. The DOJ needs your assistance in reporting optional ASAP fields that are **mandatory in California**. The **mandatory** fields are: Pharmacy DEA number (**PHA03**), Pharmacy Name (**PHA 04**), pharmacy address information (Address1 **PHA05**, City **PHA07**, State **PHA08**, Zip Code **PHA09**, Phone Number **PHA10**), California Pharmacy License Number (which we require to be reported in Field **PHA11**), Patient State (**PAT15**), Gender Code (**PAT19**), and Payment Type (**DSP16**).

Paper Submission Limitations

The California Business and Professions (B&P) Code section 1715.5 (b)(3) states impart that …"For each pharmacy which submits hard copy pursuant to this subdivision and which pharmacy averages more than 25 triplicate prescriptions per month in any six months, the Board of Pharmacy or its designee may thereafter require that pharmacy to comply with subsections (b)(1) and (2)."

B&P Code section 1715.5 (b) states "The above information shall be provided in the following format:" (1) "For each pharmacy with the capacity to do so, by on-line transmission at least every 30 days and no later than the 18th calendar day of the month following the month in which the prescription is dispensed." and (2) "For each pharmacy which does not have the capacity to transmit the information on-line, on a three and one-half inch diskette in a ASCII format or any other medium approved by the Board of Pharmacy, which diskette or medium shall be mailed or delivered to a location specified by The Board of Pharmacy, at least every 30 days and no later than the 18th calendar day of the month following the month in which the prescription is dispensed."

The DOJ mandates all pharmacies to strictly meet the above statutes by submitting the data electronically. As stated in Health and Safety (H&S) Code section 11165, you must submit your data on a weekly basis. Several software vendors have tools and software that can automate your data submission processes. AAI will not accept paper submission of controlled substance prescription data that is in violation of the above statute.

Request for CURES Data Deletion/Correction

As a result of controlled substance prescription data now available online to authorized users, more eyes are reviewing the data and identifying errors. While it has never been the Department of Justice (DOJ), Bureau of Narcotic Enforcement's (BNE) posture to change, edit, or delete CURES records or files; to overlook these errors might be more damaging than to allow the correction. Therefore, within the American Society for Automation in Pharmacy (ASAP) standards, the following procedures are being instituted:
After a Pharmacy/Dispensing Prescriber/Clinic or Software Vendor submits a file, it discovers an error:

1. The Pharmacy/Dispensing Prescriber/Clinic or Software Vendor accesses and completes the Deletion/Correction Request form, adds a digital signature, and submits electronically to AAI. This form must be completely filled out with all pertinent information before the form will be evaluated and approved for processing.

2. Upon approval by BNE, AAI will ask the Pharmacy/Dispensing Prescriber/Clinic or Software Vendor to:
   a.) Resubmit the original record with 02 (void) in DSP 01 field and include the reference number in AIR 10 field.
   b.) If applicable (not a deletion only), the pharmacy/vendor submits the corrected record with 01 (revise) in DSP 01 field.

   A copy of the Deletion/Correction Request will be sent to the California State Board of Pharmacy and/or Medical Board of California.

Please be aware that no records or data will be deleted or corrected within CURES without completion and BNE approval of the Request for Deletion/Correction of CURES Data form. The form is available on BNE's http://ag.ca.gov/bne/cures.php Website or can be obtained thru AAI by emailing them at data@aainh.com. This new process is effective **immediately!** The approximate turn around time for the data to be deleted/corrected is seven (7) days after BNE approval.

Resubmission of Corrected Data

Accurate controlled substance prescription data is vital to prescribers monitoring their patient's health. Our goal is to help pharmacies submit controlled substance prescription data without problems or errors. When you are notified by AAI that errors have occurred during the submission of your controlled substance prescription data you are required to correct the data and re-submit it to AAI.

Special Characters in the Data Fields

Please do not use pipes (|) or carets (^) in the **data fields**. Your file will be rejected if pipes (|) or carets (^) appear in the data fields.

Zero Fill

Pharmacies are required to report zero fill data to AAI when there are no controlled substance data to report. This is a mandatory weekly reporting requirement and cannot be reported in advance.

Vendor Notification

If your pharmacy uses a third-party vendor to submit controlled substance prescription data to the DOJ, your company is responsible to notify its vendor of the upcoming transition.

The DOJ will continue to strive towards creating technological advances that will improve and ease the reporting of controlled substance prescription data. Once again, I thank you for your cooperation in meeting the needs of the CURES program.

Pharmacy Email Notification/Verification of Processed Data and Rejects

The current email notification database is not currently available from the current vendor, Infinite Solutions. To avoid any delays in file notifications, you need to send an email to AAI to request email notifications for any data submissions. Please include your email address, pharmacy license and DEA numbers, pharmacy name, contact name, and phone number. You must also include 'CA Email Notifications' in the subject line.

Should you have any questions please contact **AAI at (800) 539-3370 (office) or email them at data@aainh.com.** Their mailing address is:

Atlantic Associates, Inc
8030 S. Willow St, Bldg #3
Manchester, NH 03103.

You will be notified when AAI's website is available for data submissions and find updated information for controlled substance prescription data to the DOJ and the CURES program.

If you have any further questions or need additional information you can visit the Attorney General's website at www.ag.ca.gov or you may contact the CURES Program at (916) 319-9062.

Sincerely,

Katherine Ellis

KATHERINE ELLIS, Manager
Bureau of Narcotic Enforcement

FOR EDMUND G. BROWN JR.
Attorney General

cc: Board of Pharmacy
California Medical Board

Attachment 13

GOALS, OUTCOMES, OBJECTIVES, AND MEASURES

ENFORCEMENT COMMITTEE

Goal 1: Exercise oversight on all pharmacy activities.

Outcome: Improve consumer protection.

Objective 1.1: Achieve 100 percent closure on all cases within 6 months.

Measure: Percentage of cases closed.

Tasks:

1. Complete all desk investigations within 90 days (for cases closed during quarter).

	N	< 90 days	< 120 days	< 180 days	Longer	Average Days
Qtr 1	547	145	45	80	277	276
		26%	8%	15%	51%	
Qtr 2	550	177	59	82	232	202
		32%	11%	15%	42%	
Qtr 3						
Qtr 4						

2. Complete all field investigations within 120 days (for cases closed during quarter).

	N	< 120 days	< 180 days	< 270 days	Longer	Average Days
Qtr 1	363	140	93	75	55	195
		38%	26%	21%	15%	
Qtr 2	333	113	77	81	62	181
		34%	23%	24%	19%	
Qtr 3						
Qtr 4						

Data is calculated from date received to the date the report was accepted by SI/Manager. Does not include split cases.

3. Close (e.g., no violation, issue citation and fine, refer to the AG's Office) all board investigations and mediations within 180 days.

Qtr 1	N	< 180	< 270	< 365	> 365
Closed investigations, no additional action, license approvals	407	298	45	14	50
Closed 4301 letters, license denials, withdrawn by Board	169	81	23	38	27
Cite and/or fine letter of admonishment	248	99	63	28	57
Attorney General's Office	87	25	19	13	30
Qtr 2	**N**	**< 180**	**< 270**	**< 365**	**> 365**
Closed investigations, no additional action, license approvals	424	300	59	41	24
Closed 4301 letters, license denials, withdrawn by Board	202	95	34	35	38
Cite and/or fine letter of admonishment	161	62	44	24	31
Attorney General's Office	96	25	31	14	26
Qtr 3	**N**	**< 180**	**< 270**	**< 365**	**> 365**
Closed investigations, no additional action, license approvals					
Closed 4301 letters, license denials, withdrawn by Board					
Cite and/or fine letter of admonishment					
Attorney General's Office					
Qtr 4	**N**	**< 180**	**< 270**	**< 365**	**> 365**
Closed investigations, no additional action, license approvals					
Closed 4301 letters, license denials, withdrawn by Board					
Cite and/or fine letter of admonishment					
Attorney General's Office					

Data is calculated from date received to date closed or referred to the AG.
One case may have multiple respondents. The actual number of citations and letters of admonishment issued are shown on the next page.

Objective 1.2	Manage enforcement activities for achievement of performance expectations.
Measure:	Percentage compliance with program requirements.

Tasks:

1. Administer the Pharmacists Recovery Program.

	Voluntary Participants	Participants Mandated Into Program	Noncompliant, Terminated From Program	Successfully Completed Program
Qtr 1	30	45	1	0
Qtr 2	22	55	0	6
Qtr 3				
Qtr 4				

2. Administer the Probation Monitoring Program.

	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Individuals	122	129		
Sites	10	14		
Tolled	34	29		
Inspections Conducted	51	53		
Successfully Completed	8	4		
Petitions to Revoke Filed	2	9		

3. Issue all citations and fines within 30 days.

	N	30 days	60 days	90 days	> 90 days	Average Days
Qtr 1	312	200	107	5	0	26
		64%	34%	2%	0%	
Qtr 2	263	230	11	20	2	20
		87%	4%	8%	1%	
Qtr 3						
Qtr 4						

4. Issue letters of admonishment within 30 days.

	N	30 days	60 days	90 days	> 90 days	Average Days
Qtr 1	44	35	9	0	0	21
		80%	20%	0%	0%	
Qtr 2	31	29	2	0	0	20
		94%	6%	0%	0%	
Qtr 3						
Qtr 4						

These data are actual number of citations and letters of admonishment (LOA) issued.
One investigation may have multiple licensees that are issued a citation or LOA (split cases).

5. Obtain immediate public protection sanctions for egregious violations.

	Interim Suspension Orders	Automatic Suspension Based on Conviction	Penal Code 23 Restriction
Qtr 1	1	0	0
Qtr 2	0	0	0
Qtr 3			
Qtr 4			

6. Submit petitions to revoke probation within 30 days once noncompliance with terms of probation is substantiated.

	30 days	60 days	> 60 days	N
Qtr 1	1	1	7	9
Qtr 2	5	0	0	5
Qtr 3				
Qtr 4				

Objective 1.3	Achieve 100 percent closure on all administrative cases within 1 year.
Measure:	Percentage of administrative cases closed within 1 year.
Tasks:	1. File pleadings within 90 days of referral.

	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Number of Cases Referred to Attorney General's Office	88	97		
Accusations Filed	74	46		
Statement of Issues Filed	6	10		
Petitions to Revoke Probation Filed	2	9		

2. Percentage of administrative cases closed within 1 year.

	N	1 Year	1.5 Year	2 Year	2.5 Year	>2.5 Years	Average
Qtr 1	45	19	20	2	2	2	430
		42%	44%	4%	4%	4%	
Qtr 2	70	30	21	14	1	1	390
		43%	30%	20%	1%	1%	
Qtr 3							
Qtr 4							

Objective 1.4	Inspect 100 percent of all facilities once every 3 year inspection cycle ending 6/30/11.
Measure:	Percentage of licensed facilities inspected once every 3 year cycle.
Tasks:	1. Inspect licensed premises to educate licensees proactively about legal requirements and practice standards to prevent serious violations that could harm the public.

	Number of Inspections	Aggregate Inspections This Cycle	Percent Complete
Qtr 1	404	4550	65%
Qtr 2	364	4385	63%
Qtr 3			
Qtr 4			

2. Inspect sterile compounding pharmacies initially before licensure and annually before renewal.

	Number of Inspections	Number Inspected Late
Qtr 1	50	0
Qtr 2	165	0
Qtr 3		
Qtr 4		

3. Initiate investigations based upon violations discovered during routine inspections.

	Number of Inspections	Number of Investigations Opened	Percent Opened
Qtr 1	404	7	2%
Qtr 2	364	8	2%
Qtr 3			
Qtr 4			

Objective 1.5	Initiate policy review of 25 emerging enforcement issues by June 30, 2011.
Measure:	The number of issues.
Tasks:	1. Monitor the implementation of e-pedigree on all prescription medications sold in California. *Oct. 2009:* *Executive Officer provides information about California's e-pedigree requirements at a SecurePharma Conference of drug manufacturers and wholesalers in Philadelphia and at a SpecialtyPharma Conference (contract drug manufacturers) in Phoenix.* *Dec. 2009:* *Executive Officer provides information about California's e-pedigree requirements at the Health Care Distributors Association Trace and Track Conference in Washington D.C.* *March 2010:* *Executive Officer provides information about California's e-pedigree requirements via a Webinar hosted by IBS.* *April 2010:* *Board reviews Food and Drug Administration guidance on a unique serialized identifier released March 26.* *Oct. 2010:* *Executive Officer provides information about California's requirements to a GS1 training session in San Francisco.* 2. Implement federal restrictions on ephedrine, pseudoephedrine or phenylpropanolamine products. *Sep. 2006:* *Final phase-in of federal requirements takes effect on September 30. Board newsletter provides information for licensees.* *Oct. 2006:* *Board adds Consumer friendly materials regarding sales of these drugs to its website.* 3. Monitor the efforts of the Drug Enforcement Administration and Department of Health and Human Services to implement e-prescribing for controlled substances. *Nov. 2006:* *Board submits letter supporting change in Drug Enforcement Administration policy allowing prescribers to write multiple prescriptions for Schedule II drugs with "Do not fill before (date)" at one time, eliminating the need for patients to revisit prescribers merely to obtain prescriptions.* *Sep. 2008:* *Board submits comments on Drug Enforcement Administration proposed requirements for e-prescribing of controlled substances.* *Dec. 2009:* *Executive Officer meets with DEA officials in Washington D.C. to discuss interest in e-prescribing of controlled drugs.* *April 2010:* *Board reviews proposed Drug Enforcement Administration requirements for electronic prescribing of controlled substances.* *June 2010:* *Enforcement Committee received updates on DEA rule change.* *Jan. 2011:* *Board prepares guidance document for pharmacies and prescribers.* 4. Evaluate establishment of an ethics course as an enforcement option. *Oct. 2008:* *Board holds regulation hearing on proposed requirements for the ethics class.* *Jan. 2009:* *Board adopts regulation.* *Sept. 2009:* *Regulation takes effect.* *3rd Qtr 09-10:* *Board subcommittee of two board members begins work with staff on suggested specific components and topics for the program, in compliance with board regulations.* *Oct. 2010:* *First course provided.*

5. Participate in emerging issues at the national level affecting the health of Californians regarding their prescription medicine.

Dec. 2009: *Executive Officer provides presentation on California's e-pedigree requirements to three national association meetings.*

3rd Qtr 09-10: *Board initiates rulemaking on a regulation to establish requirements for patient-centered prescription container labels (see report on Legislation and Regulation Committee's Goals, Outcomes, Objectives and Measures).*

6. Provide information about legal requirements involving e-prescribing to support the Governor's Health Care Initiative and its promotion of e-prescribing.

Sep. 2007: *Provided comments on proposed statutory requirements.*

Dec 2007: *Sought Department of Consumer Affairs' support for involvement in e-prescribing by the Administration.*
Provided comments on proposed e-prescribing initiatives.

Oct. 2008: *Executive Officer Herold joins a task force to achieve e-prescribing coordinated by the California HealthCare Foundation.*

Nov. 2008: *Board hosts conference on e-prescribing as part of department's professionals*
Achieving Consumer Trust Summit. The Medical Board and Dental Board join us as sponsors.

Jan. 2009: *Executive Officer Herold works with California HealthCare Foundation and Medical Board to plan joint activities with licensees to facilitate e-prescribing.*

March 2009: *Pharmacists and physicians in Visalia attend first of California HealthCare Foundation's public forums on e-prescribing.*

April 2010: *Board reviews Drug Enforcement Agency proposed regulations on e-prescribing of controlled substance.*

Nov. 2010: *Executive Officer provides presentations at annual California e-prescribing meeting.*

Jan. 2011: *Board prepares guidance document for pharmacies on DEA's requirements.*

7. Implement in California the Center for Medicare and Medicaid Service requirements for security prescription forms that will be required in only four months for all written Medicaid and Medicare prescriptions.

Oct. 2008: *Requirements for security forms in place..*

2nd Qtr 09-10: *Board executive staff and several board members attend California Healthcare Foundation's annual summit to implement e-prescribing.*

8. Liaison with other state and federal agencies to achieve consumer protection.

1st Qtr 07/08: *Bimonthly meetings initiated with Department of Health Care Services audit staff to investigate pharmacies and pharmacists involved in MediCal fraud and drug diversion. Several joint investigations underway with state and federal agencies.*

2nd Qtr 07/08: *Bimonthly meeting with the Department of Health Care Services continue.*
Board inspectors attend 3-day-training with federal and state regulations on items involving fraud provided by the Office of Inspector General of the Department of Health and Human Services.
Joint investigations with other state and federal agencies continue that involve the board's jurisdiction.

3rd Qtr 07/08: *Bimonthly meetings with the Department of Health Care Services continue.*
Board works with the Drug Enforcement Administration on joint investigations and receives specialized training.

4th Qtr 07/08: *Board staff meets with staff of the California Department of Public Health regarding joint inspections of licensed healthcare facilities in California to identify and remove recalled drugs.*

3rd Qtr 08/09: *Executive staff meet with Department of Health Care Services investigators on cases of mutual concern. Board investigators work with federal and state drug enforcement officers on search warrants and mutual investigations.*

4th Qtr 08/09: *Board staff meets with staff of the California Department of Public Health regarding joint inspections of licensed healthcare facilities in California to identify and remove recalled drugs.*
Executive staff meet with Department of Health Care Services investigators on cases of mutual concern. Board investigators work with federal and state drug enforcement officers on search warrants and mutual investigations.
The federal Drug Enforcement Administration provides training to board staff on new requirements for online pharmacies selling controlled substances.

2nd Qtr 09/10: *Executive staff meet with Department of Health Care Services staff on mutual investigations; DEA staff in Washington D.C. on enforcement issues involving controlled drugs; the U.S. Attorney General's office in Sacramento on two major enforcement matters; and worked with the Licensing and Certification and Food and Drug Branch of the California Department of Public Health on issues of mutual concern.*

3rd Qtr 09/10: *Board supervising inspectors work with federal, state and local law enforcement agencies on emerging enforcement issues and investigations, and worked with the Licensing and Certification and Food and Drug Branch of the California Department of Public Health on issues of mutual concern.*
Board staff redirected to complete HIPDB reporting.

4th Qtr 09/10: *Board staff continue to report to HIPDB.*

2nd Qtr 10/11: *Board supervising inspectors work with federal, state and local law enforcement agencies on emerging enforcement issues and investigations, and worked with the Licensing and Certification and Food and Drug Branch of the California Department of Public Health on issues of mutual concern.*

	9. Work with the California Integrated Waste Management Board to implement requirements for model programs to take back unwanted prescription medicine from the public. *March 2008:* *Second meeting with state agency stakeholders on developing components for model programs that conform with diverse state agency security and safety requirements.* *June 2008:* *Supervising pharmacist inspector attended a two-day multi-disciplinary conference hosted by the Integrated Waste Management Board on drug take-back programs.* *Aug. 2008:* *Executive Officer Herold speaks at conferences sponsored by the California Integrated Waste Management Board.* *Oct. 2008:* *Enforcement Committee hears presentations on drug take-back programs, medical waste management processes and the take-back of sharps.* *Board to submit comments to California Integrated Waste Management Board on model programs for take-back programs.* *Nov. 2008:* *Executive Officer provides written and verbal testimony at California Integrated Waste Management Board hearing on the model guidelines.* *Dec. 2008:* *Executive Officer participates in public hearing at the California Integrated Waste Management Board on possible changes to the model guidelines adopted by the California Integrated Waste Management Board in November.* *Feb. 2009:* *California Integrated Waste Management Board amends model guidelines to include provisions advanced by the board.* *Jan. 2010:* *Board writes article on the guidelines for publication in the next issue of The Script.* *Board executive staff attend meetings on "take back drugs" at a statewide conference of the California Integrated Waste Management Board.* *Executive Officer provides presentation on the CIWMB Model Guidelines at a meeting of 20 rural California counties.* *March 2010:* *Board publishes the guidelines in The Script.* *April 2010:* *Board inspector will collect information about take back programs in California pharmacies during inspections.* *Aug. 2010:* *Executive Officer provides information regarding board policy on drug take back programs in pharmacies to CalRecycle and its draft report on model take back programs. Written comments are later provided on behalf of the board.* *Jan. 2011:* *Board reviews final version of CalRecycle's report.*

	10. Inspect California hospitals to ensure recalled heparin has been removed from patient care areas. *4th Qtr 07/08:* *Board initiates inspections of 40 California hospitals looking for counterfeit heparin and unlicensed sales but discovers recalled heparin still in 40 percent of hospitals inspected. Board notifies the Food and Drug Administration and California Department of Public Health and initiates inspections of 533 hospitals during April-June.* *Recalled heparin is found in 94 of these facilities. Data reported to board during June Board Meeting.* *1st Qtr 08/09:* *The Script highlights problems found in heparin inspections. Citations and fines issued to facilities with recalled heparin. Work with hospitals begins to strengthen drug control within facilities.* *2nd Qtr 08/09:* *Hospitals and Pharmacists-in-Charge fined where recalled heparin was discovered by the board.* *3rd Qtr 08/09:* *First stakeholder meeting scheduled to discuss drug distribution within hospitals.* *March 2009:* *First stakeholder meeting convened.* *June 2009:* *Second stake holder meeting convened. Development of model guidelines for recalls underway.* *Sep. 2009:* *Stakeholder meeting convened.* *Recall guidelines evaluated and additional comments solicited.* *Jan. 2010:* *Board reviews final version of recommended steps for addressing recalls in hospitals.* *April 2010:* *Manuscript of addressing recalls in hospitals completed, compiled into finished report and posted on Website.* *Executive officer works with the Healthcare Distributors Management Association (representing drug wholesalers) to secure notices of recalls more timely to share with board subscriber list.* *Appeals of citations and fines nearly complete.* *May 2010:* *Outstanding enforcement/compliance completed.*

11. Promulgate regulations required by SB 1441 (Ridley-Thomas, Chapter 548, Statutes of 2008) for recovery programs administered by Department of Consumer Affairs health care boards.

4th Qtr 08/09: *Draft proposals for required components 1-6 developed.*

1st Qtr 09/10: *Draft proposals for required components 7-13 developed.*

3rd Qtr 09/10: *Board hears presentation on uniform standards. Staff/counsel identifies changes required to implement standards.*

1st/2nd Qtr 10/11: *Proposed changes to Board Disciplinary Guidelines drafted. Staff continue working with DCA on standards.*

12. Develop and release Request for Proposal for vendor for Department of Consumer Affairs health care boards that operate license recovery programs.

4th Qtr 08/09: *Provisions for Request for Proposal developed: Request for Proposal released.*

2nd Qtr 09/10: *Contract awarded.*

13. Participate in Department of Consumer Affairs Consumer Protection Enforcement Initiative to strengthen board enforcement activities and reduce case investigation completion times for formal discipline.

1st & 2nd Qtr 09/10: *Work with Department of Consumer Affairs on identification of Enforcement Best Practices.*
Board discusses SB 1441 components for Diversion Programs to strengthen consumer protection enforcement staff attend Enforcement Best Practices work group.

3rd Qtr 09/10: *Board senior staff and Board President meet with Department of Consumer Affairs to discuss enforcement program enhancements in SB 1111.*
Board staff begin submitting monthly reports detailing workload and improvement efforts to the department.

4th Qtr 09/10: *Board hears presentation on CPEI and current status of department and board efforts.*

1st/2nd Qtr 10/11: *Board conducts civil service exams for inspector and supervising inspector classifications. Hiring freeze prevents hiring of staff.*

14. Initiate criminal conviction unit to review and investigate rap sheets received on licenses for arrests or convictions.

1st Qtr 09/10: *Unit created via budget change proposal, 6.5 staff hired, trained, initiate work.*
There are 1,287 rapsheet investigations under review.

2nd Qtr 09/10: *There are 1,037 rapsheet investigations under review.*

3rd Qtr 09/10: *There are 652 rapsheet investigations under review.*

4th Qtr 09/10: *Post implementation review of Criminal Conviction Unit completed.*
Enforcement Committee advised of new unit outcomes.

15. Complete comprehensive review of investigative and enforcement internal processing to identify process improvements.

1st Qtr 09/10: *Board staff implemented on-line assignment of investigations.*
Board staff implemented on-line review of draft pleadings.

2nd Qtr 09/10: *Board staff began drafting Default Decision and Orders.*

4th Qtr 09/10: *Board staff began drafting Petition to Revoke Probation Pleadings.*
Board staff implemented a pilot program to provide pre-populated investigation reports to the Compliance Team.

	16. Complete review of pharmacies dispensing prescriptions for Internet web site operators. *2010: Updates on disciplinary actions provided at board meetings and in The Script.* 17. Provide updates on the board's reporting to the Healthcare Integrity and Protections Data Bank (HIPDB). *1st Qtr 10/11: 656 reports submitted (includes initial and revised submissions).* *2nd Qtr 10/11: 334 reports submitted (includes initial submissions).*